Submitter : Ms. M.B. Schuh **Date:** 09/14/2005

Organization : St. Anthony's Medical Center

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

In the IPPS rules they address "Yearly Review for Making DRG Changes; Request for Public Comment" and ask that concerns about DRG classification issues be brought to CMS' attention no later than early December. I cannot find a similar request for public comment in the OPPS rules and would like to request CMS consider making this part of the rule announcements. Thank you.

Submitter : **Dr. Kimberly Kerr** **Date: 09/14/2005**

Organization : **Tower Surgical**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

On behalf of the following physicians, who are all involved in wound care in Indiana, we wanted to bring your attention to an error.

Kim Kerr, MD
Tower Surgical

Ryan Nachreiner, MD
Indiana University Vascular Surgery

Vincent Scavo, MD
Indiana Ohio Cadiovascular Surgery

Alan Ladd, MD
Indiana University Pediatric Surgery

Don Selzer, MD
Indiana University General Surgery

Mike Baker, DPM
Westview Wound Care Center

Derek Lou, MD
Indiana University Plastic Surgery

Andy Isch, MD
Naab Road General Surgery

Regarding CMS-1501-P:

We are aware that through a technical error, payment rates for Apligraf and Dermagraft are scedulcd to be significantly cut in 2006. Please understand that these products are vital to wound care and therefore to our patients, who are your customers. As currently scheduled, we (hospitals, etc.) would not be able to continue to use the products due to the sub reimbursement (significantly less than the cost of the products). This would be a dire problem for the aging population with wounds, and for their sake, please correct this error so that both products remain available for use.

Sincerely,

Kim Kerr, MD
Tower Surgical
1801 N. Senate Blvd, Suite 635
Indianapolis, IN 46202
(317) 923-7211

Submitter : Carla Terry **Date:** 09/14/2005

Organization : Idaho Hospital Association

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attachments

CMS-1501-P-402-Attach-1.DOC

CMS-1501-P-402-Attach-2.DOC

Specific comments

APC Relative Weights

Current law requires that CMS review and revise the relative payment weights for APCs at least annually. The IHA continues to support the agency's use of hospital data, and not data from other sources, to set the payment rates, as this information more accurately reflects the costs hospitals incur to provide outpatient services. However, since the implementation of the OPPS in August 2000, payment rates for specific APCs have fluctuated dramatically. For 2006, the proposed rates continue to show significant volatility. There are several reasons for these changes.

First, in the proposed rule, CMS uses the most recent claims data for outpatient services to set 2006 weights or rates, using approximately 49 million whole claims for hospital outpatient department services furnished during calendar year 2004 to create 81 million single records. **The IHA continues to support the use of the most recent claims and cost report data to set the 2006 payment weights and rates.**

Second, CMS continues its efforts to include more claims data in the calculation of the APC payment rates, especially those "multiple procedure claims" that contain charges for more than one service or procedure. CMS is proposing to expand the number of Healthcare Common Procedure Coding System (HCPCS) codes it bypasses on a claim – from 383 in 2005 to 404 in 2006 – for the purposes of creating "pseudo" single-procedure claims. This list of bypassed codes was developed using an empirical approach established in 2005 and described in the rule. CMS also proposes to continue using "date of service matching" – in which charges are attributed to separately payable HCPCS codes based on the code's date of service – as a tool for creation of "pseudo" single claims. **In general, the IHA continues to support the use of multi-procedure claims, as we believe that these data improve hospital cost estimates. The IHA supports the expanded list of codes for bypass, as it appears unlikely that these codes would have charges that would be packaged into other services or procedures. We also continue to support the use of "date of service matching" in the development of the 2006 outpatient payment rates.**

However, the IHA is concerned that, while the proposed rule provides a detailed description of the methodology employed to calculate the APC weights, it does not provide adequate information for hospitals to evaluate the impact of each of the proposed policy changes independently or in combination. Questions like, "What would the weights be without the changes?" and "How much of the volatility in the weights is due to the changes?" cannot be answered due to this lack of data. **The IHA requests that CMS provide a public use file that shows the impact of each individual proposed change in methodology so health care providers can review the file to determine how the changes would affect their own operations, and provide a basis for submitting thoughtful comments to CMS.**

In addition, although we understand the empirical criteria used to determine the additional codes to add to the bypass list we find it puzzling that the bypass list includes

some office visit and consultation services codes but not all of them. For instance, the list includes HCPCS codes 99213 and 99214, but not 99211, 99212, and 99215. One could speculate that this might be explained, in part, by the continuing lack of consistency across hospitals in the use of the evaluation and management (E/M) codes due to the absence of uniform guidelines for hospital coding of E/M services. **The IHA seeks clarification regarding why only some of the office visit and consultation service E/M codes are included in the bypass list.**

Proposed Changes to Packaged Services: The IHA commends CMS and the APC Panel's Packaging Subcommittee for initiating a process to address provider concerns that many packaged services ("N" status code services) could be provided alone, without any other separately payable services on the claim. Currently when hospitals provide services described by these "N" status codes alone, there is no way to be reimbursed for the costs of providing these services. **We would strongly encourage CMS to continue to work with the APC Panel's Packaging Subcommittee in order to conduct further review of "N" status codes for the purpose of identifying those that should be separately payable.**

Partial Hospitalization

The IHA is concerned that the 15 percent reduction in the per diem payment rate for partial hospitalization services that CMS proposes for 2006 could have serious negative consequences for the financial viability of partial hospitalization services in hospitals and health care systems and could endanger Medicare beneficiary access to these critical services. These are services that are already quite vulnerable, with many programs closing or limiting the numbers of patients they can accept in recent years.

We share CMS's concern about volatility of the community mental health center (CMHC) data and support the agency's intent to monitor CMHC costs and charges for these services and to work with CMHCs to improve their cost reporting so that payments can be calculated based on better empirical data.

Although the IHA recognizes that CMS's proposal was made in order to avoid an even more significant reduction in the payment rate for these services, we do not believe that hospitals that offer partial hospitalization services should be penalized for the instability in data reporting that stems from CMHC-based services. **Instead, the IHA recommends that in the final rule for 2006, CMS freeze payment rates for partial hospitalization services at the 2005 levels. This approach will provide for payment stability for these services and protect beneficiary access while allowing CMS adequate time to address the instability in the CMHC data.**

Conversion Factor

The IHA assumes that CMS will again follow the practice it has used in previous years of utilizing the same market basket update published in the final inpatient PPS final rule for the purposes of the outpatient PPS. As part of this we note that in the inpatient final rule, as requested by IHA, CMS changed the market basket estimation methodology to provide

a better estimate of hospitals cost increases. We assume that this change will also be carried forward into the final outpatient rule.

Expiring Hold Harmless Provision for Transitional Corridor Payments for Certain Rural Hospitals

The IHA is concerned about the impact the expiration of the transitional corridor hold harmless payments will have on small rural hospitals. These are vulnerable facilities that provide important access to care for populations in their communities. The AHA is working with members of Congress on legislation that will permanently extend hold harmless payments to small rural hospitals and rural sole community hospitals, as is currently the case for cancer hospitals and children's hospitals.

Rural Hospital Adjustment

In the proposed rule, CMS discusses the study it conducted, in compliance with Section 411 of the Medicare Modernization Act (MMA), to determine if rural hospital outpatient costs exceed urban hospital outpatient costs. As part of this discussion, CMS noted that it conducted an explanatory regression analysis that included three specific classes of rural hospitals – rural sole community hospitals (SCHs), rural hospitals with less than 100 beds that are not rural SCHs, and other rural hospitals. CMS conducted this analysis in order to determine whether the small difference in costs that it found between rural versus urban hospitals in it initial regression analysis was uniform across rural hospitals or whether all of the variation was attributable to a specific class of rural hospitals. The results of this explanatory regression analysis led CMS to its conclusion that rural SCHs are more costly than urban hospitals and therefore CMS proposes to provide for a 6.6 percent payment increase for rural SCHs for 2006.

The IHA is concerned that Table 6 in the proposed rule, which includes the results of this analysis, does not separately set out the regression results for rural hospitals with 100 or fewer beds that are not rural SCHs. While CMS implies in the preamble text that the results for this category of hospitals were not significant, we believe that is important to report the results for these hospitals, as they will be the facilities that will be losing their hold-harmless protection in 2006. **Therefore, we urge that, in the final rule, CMS either present in Table 6 the regression results for rural hospitals with 100 or fewer beds that are not SCHs or explain why they cannot report these results.**

The IHA also seeks clarification on three issues: (1) Would a SCH located in a rural area, which has been reclassified for wage index purposes into an urban area be eligible for the SCH adjustment? (2) Would a SCH located in an urban area, which has been reclassified for wage index purposes into a rural area be eligible for the SCH adjustment? (3) Would rural SCHs participating in the Rural Community Hospital (RCH) demonstration program be eligible for this adjustment?

Outlier Payments

Outlier payments are additional payments to the APC amount to mitigate hospitals' losses when treating high-cost cases. For 2006, CMS proposes to reduce the outlier pool to one percent of total outpatient PPS payments. Further, CMS asserts that the fixed-dollar

threshold should be increased by $400 to $1,575 in order to ensure that estimated 2006 outlier payments would equal one percent of total outpatient PPS payments. Therefore, in order to qualify for an outlier payment, the cost of a service would have to be both more than 1.75 times the APC payment rate and at least $1,575 more than the APC rate.

While the IHA supports the continued need for an outlier policy in all prospective payment systems, including the outpatient PPS, we are concerned about whether CMS has set the thresholds for outliers in this rule too high. The IHA seeks further clarification from CMS regarding how the agency determined that a $400 increase in the fixed-dollar threshold was appropriate and how the $1,575 fixed-dollar threshold was calculated.

In addition, for the past four years, CMS set aside 2 percent of total estimated outpatient PPS payments to fund outlier payments to hospitals. For 2006, CMS is proposing to set aside only one percent for outliers. However, CMS does not publicly release data regarding how much of the outlier set-aside was actually spent in prior years in the *Federal Register* or on its Web site. With the significant changes to outlier policies proposed for 2006, the IHA is concerned that Medicare may not actually spend the outlier target set-aside.

Therefore, the IHA strongly recommends that in the final rule CMS publish data on actual outlier payments made in 2004 and prior years, that actual outlier payments for 2005 be reported as soon as CMS is able to obtain complete data and that CMS continue to report this data into the future. If CMS is able to obtain this information on the inpatient side and publicly report it, we do not understand why it cannot be similarly obtained and reported on the outpatient side. Interested parties should not have to purchase costly databases in order to determine whether these thresholds are being set at the right level. Even if CMS believes that it does not have a statutory mandate to return unspent outlier pool funds to the outpatient PPS system, we believe that CMS has a duty to make appropriate estimates and we are concerned that CMS cannot set the outlier threshold at an appropriate level if it does not know what is actually being spent on outliers.

In issuing a public accounting of total outlier payments for 2005, CMS will need to take into consideration the implications of an error that occurred in identifying services that qualified for outlier payments. CMS incorrectly set the outlier threshold too high in the 2005 fiscal intermediary system, which resulted in underpayment for outliers. Providers were requested to identify and re-bill those claims that should have received outlier payments. These additional outlier payments should be considered in its calculation of actual outlier expenditures for 2005.

<u>New Technology</u>

The IHA supports CMS's proposal to require that an application for a code for a new technology service be submitted to the American Medical Association's (AMA's) CPT Editorial Panel before CMS accepts a New Technology APC application for review.

As we have previously noted in comment letters and verbally before the APC Advisory Panel, the proliferation of G codes and C codes with potentially overlapping descriptions with CPT codes is confusing and burdensome for hospital coders. This confusion has often resulted in incorrect coding and unreliable data available for rate setting. Requiring that an application for a new CPT code be submitted at the time of a New Technology APC application will minimize the need for expedited issuance of temporary G or C codes. HCPCS level II G and C codes are generally not accepted by payers other than Medicare, thus requiring hospitals to have two different codes to report the same procedure depending on the payer. This new process will reduce the duplication of codes so that it will start the process right via CPT rather than starting with a New Technology assignment without a way to report the procedure. While we understand that there may still be circumstances when a G or C code will still be required, having a CPT code available for new technology will simplify the billing and coding process for hospitals because then they will be using one set of codes (i.e. CPT) for all payers as much as possible.

Device manufacturers may not be planning ahead and applying for CPT codes for a variety of reasons, including fear of application denial. In any event, the CPT process involves a more rigorous process than level II HCPCS codes and includes the opportunity for input from the physician specialty societies. Without support from the physician specialties that would embrace the new technology, it is doubtful that the new technology will achieve acceptance from the medical community. Input from the physician community also ensures that the code descriptor selected for new technology procedures will be as close as possible to the terminology that physicians will use to document these services. This in turn will reduce the confusion in determining proper code selection.

Hyperbaric Oxygen

The IHA supports CMS's decision to no longer use the respiratory therapy CCR for purposes of calculating the median cost for hyperbaric oxygen therapy (HBOT) and instead use the hospital's overall CCR. However, as some hospitals currently report their costs for HBOT in a separate HBOT line on their cost report, the IHA would recommend that for 2006, CMS calculate the median rate for HBOT using the HBOT CCR for those hospitals that have such separate reporting, and use the overall hospital CCR otherwise. In order to develop more accurate rates for HBOT in the future, CMS should encourage hospitals to report their HBOT costs on a separate HBOT line on their cost report. This should not be administratively difficult for hospitals because HBOT revenues are already captured in a specific separate revenue code, so this would involve only a change in where costs for HBOT are reported on the cost report.

Non-Pass-Throughs

The MMA requires that in 2006, payment for specified covered outpatient drugs be equal to the average acquisition cost for the drug, subject to any adjustment for overhead costs. In the proposed rule, CMS evaluates three alternatives for setting 2006 payment rates for these drugs: (1) average and median purchase price data for drugs purchased from July 1, 2003 to June 30, 2004 derived from a General Accountability Office survey of 1,157

hospitals; (2) the average sales price (ASP) data from the fourth quarter of 2004; and (3) mean and median costs derived from the 2004 hospital claims data. After considering the merits and weaknesses of each approach, CMS proposes to pay ASP+6 percent for separately payable drugs and biologicals in 2006.

In general, the IHA supports this proposal and agrees that paying for drugs at ASP+6 percent appears to be the best estimate of average acquisition cost available at this time. This also has the additional benefit of providing for consistent payment rates across the hospital outpatient PPS and the physician fee schedule payment systems. Finally, given the inflation in drug prices over time, we believe that the ability to update ASP rates on a quarterly basis is also a key advantage of this proposal. However, the proposal to pay at ASP+6 percent will result in significant reductions in payments for some separately payable drugs and biologicals.

Therefore, the IHA supports the APC Panel's recommendation that CMS carefully track the drug codes to be paid at ASP+6%, with a particular focus on those drugs whose rate would fall significantly in 2006. We are concerned that steep drops in payments for certain drugs and biologicals could have implications on manufacturer production levels of these drugs and could adversely affect patient access to some drug therapies. If CMS obtains evidence that access to certain drug therapies would be threatened due to declines in payment rates, then it should consider freezing payments or otherwise limiting decline in payments for these products.

Pharmacy Overhead and Drug Handling Payment Rate Adjustment

In the proposed rule, CMS considers Medicare Payment Advisory Commission (MedPAC) recommendations on adjusting the APC rates for separately payable drugs to take into account pharmacy overhead and drug handling costs. CMS proposes to establish three distinct HCPCS C-codes and corresponding APCs for drug handling categories to differentiate overhead costs for drugs and biologicals and to instruct hospitals to charge the appropriate pharmacy overhead C-code for overhead costs associated with each administration of each separately payable drug and biological based on the code description that best reflects the service the hospital provides to prepare the product for administration to a patient. Since CMS does not have separate hospital charge data on pharmacy overhead, in 2006 the agency proposes to pay for these costs based on 2 percent of the ASP. This would result in overall drug payments, including the drug itself and the associated handling payment, of ASP+8%, which is a rate that CMS states is equivalent, on average, to the mean cost for drugs derived from hospitals claims data.

The IHA agrees with the MedPAC finding that handling costs for drugs and biologicals delivered in the hospital outpatient department are significant and should be reimbursed by Medicare. We believe that, while imperfect, the ASP+2 percent adjustment for drug handling would be appropriate as a temporary measure. In the future, CMS should work with hospital and pharmacy stakeholders to develop an approach to establish differential add-on payments for drug handling costs to account for a wide variety of drug handling categories.

The IHA is strongly opposed to CMS' proposal to require hospitals to establish separate charges for pharmacy overhead for separately payable drugs and biologicals and to utilize the three proposed C-codes for charging these overhead costs. This would be extremely burdensome for hospitals to operationalize.

There are many complex issues and administratively burdensome aspects to adopting CMS proposal for charging for drug handling through the use of these new C-codes. The most important of these issues is that Medicare providers are required to maintain uniform charges for all payers. Given this, it is impossible to charge Medicare for a drug at a rate that does not reflect handling cost and charge other payers for the same drug at a higher rate that does reflect handling costs. This simply could not be done. Even assuming that hospitals could provide differential charges, other concerns include:

- Hospitals will have to evaluate the normal mark-up formula for all pharmacy items and pull out the handling costs for some, but not all, of these drugs and biologicals. That is, hospitals would have to identify and strip out the handling charges for separately payable drugs under Medicare while the drug handling charges for packaged drugs would remain incorporated within the overall charge for the drug. This would be an extremely complex and time-consuming process.
- For each separately payable drug, hospitals will need to assign the handling charge to one of CMS's proposed new drug handling C-codes. These C-codes are only recognized by and acceptable to Medicare, but not to other payers. Hospitals will therefore have to modify their billing systems to separate out the drug handling from the drug charge for Medicare claims but bill them as a single line item for other payers. Setting aside the concern raised above about violating the Medicare requirement for uniform charges, this also introduces another level of complexity and burden to this proposal.
- There is confusion about how the dug handling C-codes would apply when a hospital pharmacy mixes multiple doses of a drug for a patient. Would the hospital report a single C-code for handling costs in this case or multiple C-codes? Confusion around how to charge could result in aberrant data, which would make it difficult to establish appropriate payment rates for these services in the future.
- Drug pricing is generated via a pharmacy charging system that is often located outside the hospital's normal charging system and may not be able to accommodate the CMS proposed C-codes.
- Many hospitals use the same charge master for inpatient and outpatient services. If the handling charge must be separated out of the drug charge for the outpatient setting, there are questions about how CMS will expect providers to report drug charges in the inpatient setting versus the outpatient setting.

The IHA is also aware that the APC Panel, based on testimony provided by a number of organizations representing drug manufacturers and others, has proposed that CMS expand the application of its proposed drug handling coding and payment methodology to drugs that are packaged into other APCs. **The IHA strongly opposes this expansion of the drug handling C-coding proposal to packaged drugs. This would exponentially**

increase the coding and administrative burden on hospitals due to the sheer number of drugs that would require special charging practices for Medicare purposes. In addition, hospitals generally do not provide detailed billing for drugs that are not separately paid, meaning that hospitals do not separately assign HCPCS C-codes or J-codes for these drugs. It would therefore be extremely difficult for hospitals to bill the right drug handling C-code for packaged drugs. Further, many hospitals that have adopted a paperless billing system also use an imaging system to generate a bill for a patient. Given the large volume of drugs used in hospital outpatient departments, expanding the drug handling coding requirements to all these drugs, regardless of their packaging status, would dramatically increase hospital administrative costs associated with this already misguided proposal.

The IHA strongly recommends that CMS *not* implement the proposed drug handling C-codes in 2006. Instead, we recommend that CMS work with stakeholder groups to collect further data and develop alternative and simpler solutions for ensuring that hospitals are appropriately paid for their pharmacy overhead and drug handling costs. Such an approach should incorporate the payments for drug handling directly into the payment rate for the drug itself, rather than requiring separate coding systems. The AHA would be pleased to convene a group of member hospitals to work with CMS and with the APC Advisory Panel to discuss possible alternatives.

If CMS decides to proceed with implementing this burdensome drug handling C-codes policy, then IHA strongly suggests that CMS provide for a grace period of no less than 6 months after implementation of the 2006 outpatient PPS (June 1, 2006) to allow hospitals to make system changes and educate pharmacy staff, hospital finance staff, and coders on the required use of the drug handling "C" codes.

<u>Drug Administration</u>

The IHA continues to support CMS' proposal to use CPT codes to bill for drug administration services provided in the hospital outpatient department. Using CPT codes simplifies the administrative burden for the coding of drug administration since hospitals can use the same codes for Medicare and non-Medicare payers. We understand that under the proposed methodology, payment for services within the same APC would be collapsed by the OCE into a single per-visit APC payment—just as it currently does—until 2005 claims data becomes available and CMS is able to provide further refinement and recognize resources associated with drug administrations lasting several hours.

Because of the significant changes expected with the new 2006 CPT codes for drug administration, hospitals will need instruction and clarification on the application of these new codes. For example, clarification will be needed regarding the following:

- How the code application may be similar or different for the hospital outpatient department as compared to the physician setting—especially with regards to non-oncology providers of infusion and injection services since they often cross departments.

- Definitions of what constitutes an "initial" vs. subsequent infusion vs. concurrent infusion.
- Definition of "hydration" and how is it different from a hydration that is given for therapeutic reasons. In other words, a therapeutic infusion can be hydration.
- How should infusions or titrations be reported? Many times they are established with a documented start time and are administered via pump. As such, many infusions are maintained by equipment function rather than manual intervention. In these cases, a nurse may be aware of the start time of an infusion and may document it however, it is unlikely that the stop time will be documented.

The AHA would welcomes the opportunity to work with CMS on coding education, as well as on the development of appropriate future rates for drug administration in hospital outpatient departments.

E/M Services

Since the implementation of the outpatient PPS, hospitals have coded clinic and emergency department (ED) visits using the same CPT code as physicians. CMS has recognized that existing E/M codes correspond to different levels of physician effort but do not adequately describe non-physician resources. Although hospitals were anticipating that CMS would propose a national, uniform E/M coding system in 2003, the agency chose not to do so. As a result, in 2003 the AHA and the American Health Information Management Association convened an independent panel of experts to develop a set of coding guidelines for CMS.

Specifically, the panel recommended that CMS should:

1. Make payment for emergency department and clinic visits based on four levels of care.
2. Create HCPCS codes to describe these levels of care as follows:
   - Gxxx1 - Level 1 Emergency Visit
   - Gxxx2 - Level 2 Emergency Visit
   - Gxxx3 - Level 3 Emergency Visit
   - Gxxx4 - Critical Care provided in the Emergency Department
   - Gxxx5 - Level 1 Clinic Visit
   - Gxxx6 - Level 2 Clinic Visit
   - Gxxx7 - Level 3 Clinic Visit
   - Gxxx8 - Critical Care provided in the Clinic
3. Replace all the HCPCS currently in APCs 600, 601, 602, 610, 611, 612, and 620 with GXXX1 through GXXX8.
4. Crosswalk payments from GXXX1 to APC 610, GXXX2 to APC 611, etc.

In the 2004 and 2005 rules, CMS stated it was considering proposed national coding guidelines recommended by the panel, and planned to make any proposed guidelines available on the Outpatient PPS Web site for public comment. CMS also proposed to implement new E/M codes only when it is also able to implement guidelines for their use.

This guidance would be issued after ample opportunity for public comment, systems change and provider education.

The IHA is disappointed that the 2006 proposed rule again does not propose national guidelines for facility E/M reporting. While we are glad that CMS continues to develop and test the new codes, hospitals are still without a standard methodology for reporting E/M services. This lack of uniformity not only puts hospitals at compliance risk for multiple interpretations of the level of service that should be coded and billed, but also affects CMS' ability to gather consistent, meaningful data on services provided in the emergency department and hospital clinics. This is especially important because CMS uses the mid-level clinic visit (APC 601) as the anchor for establishing the relative weights within the outpatient PPS, and, due to a lack of national coding guidelines, there is no agreement on what a mid-level clinic visit encompasses. We believe that the E/M coding recommendations made by the independent panel will adequately meet hospitals' needs.

Blood and Blood Products

CMS proposes to continue to make separate payments for blood and blood products through individual APCs for each product. The agency also proposes to establish payment rates for blood and blood products based on their 2004 claims data, utilizing an actual or simulated hospital blood-specific cost-to-charge ratio to convert charges to costs for blood and blood products. For blood and blood products whose 2006 simulated medians would experience a decrease of more than 10 percent in comparison to their 2005 payment medians, CMS is proposing to limit the decrease in medians to 10 percent.

While this approach results in modest payment increases for many blood and blood product APCs, the payment rate for leukocyte-reduced red blood cells (APC 0954), the most commonly transfused blood product, and rates for certain other blood and blood product APCs will continue to decline under this methodology. According to data from the American Association of Blood Banks, the proposed rate for several of these blood products is significantly below hospitals' actual acquisition cost for blood, most notably for leukocyte-reduced red blood cells, and, with the introduction of additional blood safety measures, it is likely that the cost of these products will continue to increase, making the proposed Medicare payment rate even more inadequate.

To ensure continued beneficiary access to all blood and blood products, the IHA recommends that CMS set 2006 rates at *the greater of*: (1) the simulated medians calculated using the 2004 claims data; or (2) the 2005 APC payment medians for these products.

The IHA would also like to commend CMS for issuing the comprehensive and clear billing guidelines for blood and blood products in March of 2005, addressing issues such as the blood deductible and differences between donor and non-donor states. This document was well-received by hospitals and we believe that it will help to clear up much of the confusion regarding the correct way to code and bill for blood and blood

products. The IHA will continue to work with and educate our member hospitals, using CMS's blood billing guidelines, regarding appropriate blood coding and billing practices.

Observation Services

Currently, Medicare provides a separate observation care payment for patients with congestive heart failure (CHF), chest pain, and asthma. In order to reduce administrative burden on hospitals when attempting to differentiate between packaged and separately payable observation services, CMS proposes to discontinue current HCPCS codes for observation services (G0244, G0263, and G0264) and instead create two new HCPCS codes to be used by hospitals to report all observation services: GXXXX (Hospital observation services, per hour) and GYYYY (Direct admission of patient for hospital observation care). CMS would shift determination of whether or not observation services are separately payable under APC 0339 from the hospital billing department to the outpatient PPS claims processing logic contained in the Outpatient Code Editor (OCE) system.

The IHA supports the concept of allowing the OCE logic to determine whether services are separately payable as this will result in a simpler and less burdensome process for ensuring payment for the provision of covered outpatient observation services. As we stated in the hospital outpatient PPS in 2003, the existing G codes for observation services, with their long, complex descriptors that encompassed all variables required for claim processing into a single code, create a significant administrative burden for hospital coders and billers. We are very pleased that CMS has found a method to reduce the burden by simplifying the G codes required for observation services and making changes to the OCE logic.

However, we believe that the OCE logic could be used even more efficiently so as to make the HCPCS code GYYYY (Direct admission of patient for hospital observation care) unnecessary. If the hospital bills the GXXXX code and the claim *does not* include a 45X (emergency department) or 516 (urgent care center) revenue code, then OCE logic should determine that this was a direct admission to observation care. If the hospital bills the GXXXX code with a 45X or 516 revenue code, then it is clear that the patient came in through ED or urgent care center. Once such logic is programmed into the OCE, it would be up to the system to determine whether the observation is a result of a direct admission or not and pay accordingly.

Further, the IHA seeks clarification regarding the reference to inpatient status in the statement on page 42743 in the proposed rule that states "That is, hospitals would bill GXXXX when observation services are provided to any patient admitted to 'observation status,' regardless of the patient's status as an *inpatient* [emphasis added] or outpatient." We are concerned about this statement because if a patient is admitted as an inpatient, the hospital would not report HCPCS codes, but instead would be using the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) codes since ICD-9-CM is the Health Insurance Portability and Accountability Act code set standard for reporting procedures for hospital inpatient reporting.

Inpatient Procedures

CMS proposes to remove 25 codes from the "inpatient only" list – a list that identifies services that are unable to receive payment if they are performed in an outpatient setting and assign them to clinically appropriate APCs.

The IHA continues to urge CMS to eliminate the "inpatient only" list. Physicians, not hospitals, determine where procedures can be safely performed, as well as whether a patient's condition warrants an inpatient admission. If a physician determines that a service can be safely performed in an outpatient setting, under current rules, the hospital is penalized if that procedure happens to be on the "inpatient only" list.

If the "inpatient only" list is not eliminated for 2006, CMS should consider developing an appeals process to address those circumstances in which payment for a service provided on an outpatient basis is denied because it is on the "inpatient only" list. This would give the provider an opportunity to submit documentation to appeal the denial, such as physician's intent, patient's clinical condition, and the circumstances that allow this patient to safely be sent home without an inpatient admission.

Ancillary Outpatient Services

In the proposed rule, CMS expresses concern about the increase in the volume of hospital claims that are billed with the –CA modifier from 2003-2004, growing from 18 to 300 claims over that 1-year period. This modifier was initially used in 2003 to address situations where a procedure on the "inpatient only" list must be performed to resuscitate or stabilize a patient in a hospital outpatient department with an emergency, life-threatening condition and the patient dies before being admitted as an inpatient. In addition, CMS states that a clinical review of the claims reported using this modifier support their concerns regarding the increased modifier volume and hospitals' possible incorrect use of the modifier for services that do not meet the payment conditions CMS established.

The IHA agrees that the –CA modifier should be used only in unusual and rare circumstances. It is unclear why CMS has seen such a substantial increase in the use of the –CA modifier. It could be that hospitals are using the modifier incorrectly. The increased volume may also be a result of this being a relatively new modifier and hospitals were only beginning to become aware of it. In addition, there may be circumstances that could explain the fact that few of the claims also include a clinic or emergency department visit on the same date of service as the procedure appended with a –CA modifier. For instance, Medicare beneficiaries may have arrived for a scheduled procedure and, due to complications developing, the physician found it necessary to provide a service that they had not otherwise intended to perform in an outpatient setting.

The IHA believes that the –CA modifier policy supports an important function for hospitals that should be preserved. However, it appears that hospitals would benefit from additional education on the appropriate use of the –CA modifier. **In collaboration with CMS, the AHA will provide further education to hospitals through its Coding**

Clinic publication. In addition, we support CMS' continuing to closely monitor hospital use of this modifier.

Multiple Diagnostic Imaging Procedures

CMS proposes reducing payment when multiple imaging services are provided on the same day. In accordance with a recommendation from the Medicare Payment Advisory Commission (MedPAC), CMS proposes to make full payment for the highest paid imaging service and pay 50 percent of the APC payment rate for every additional procedure within the same "family" of procedures performed in the same session. The proposed rule outlines 11 "families" of imaging procedures by imaging modality and by contiguous body area.

The IHA opposes moving forward with this policy without a better justification and more substantial, hospital-based data to support the policy. In developing this policy, CMS did not examine hospital cost data. Rather, the agency relied on Medicare physician fee schedule practice expense data for determining the level of the discount. No evidence has been presented to justify the reduction in payment or to suggest that the 50 percent discount represents the right level of efficiencies, if they exist.

Furthermore, CMS uses different methods to set payments in physician offices and hospital outpatient departments. The physician fee schedule amounts are based on expert opinion of the resources required to perform different services while the outpatient rates are set based on hospital cost data. Hospital cost data may already reflect efficiencies gained when multiple images are performed, leading to lower costs estimates across all procedures. In addition, hospitals conduct imaging procedures in unique circumstances not found in physician offices, such as in emergency rooms and urgent care circumstances. We urge CMS to conduct analyses using hospital data before implementing this policy.

We are also concerned with how this policy will be implemented and the lack of detail provided in the proposed rule. For example, what exactly is meant by "the same session?" During a suite of tests or an emergency stay, a patient may have an imaging procedure done in the morning, followed by medical review or other tests that indicate the need for a procedure from the same "family" later in the day. In this case, the tests would not be performed at the same time, or even perhaps in the same part of the hospital, and would be incorrectly subject to the discount. The APC advisory panel discussed use of modifier '59 (separate procedure) for this purpose but rejected it as too burdensome because it would require hospitals to track patients through the course of a day. Regardless of modifier use, this policy would increase burden on hospitals because they would need to maintain two sets of charges, both with and without the discount.

Finally, the proposed rule states that this policy will be budget neutral. However, no detail is provided on how the impact of the multiple imaging procedures discount was estimated or how the budget neutrality factor was adjusted to account for this. What

share of imaging procedures did CMS estimate to be multiple imaging procedures? How were they defined? Will CMS analyze the data later to see if the estimates were correct?

Finally, AHA analysis of the impact of the policy suggests that it would reduce overall payments for imaging services by almost $250 million. Certain services, such as those in APC 0283 (Computerized Axial Tomography with Contrast Material) would see greater decreased than others. Our analysis suggests that this policy could have significant distributional impact on hospitals, depending on the volume and type of imaging services they provide.

In conclusion, the IHA agrees with the APC advisory panel recommendation that this policy should not be implemented without additional analysis and better substantiation.

Interrupted Procedures

CMS proposed to decrease payment from 100% to 50% for interrupted procedures coded with modifiers 52 (discontinued procedure, no anesthesia provided) or 74 (procedure discontinued after administration of anesthesia). However, no analysis was conducted to support the reduction.

These modifiers cannot be used for elective cancellations; therefore, the procedures generally have been interrupted for clinical reasons. In the event that a procedure is interrupted because a patient is having medical problems, costs may actually increase, not decrease, as the team addresses the patient's needs. Detailed claims analysis is needed to determine whether these additional costs could be covered through additional billed services or not. In any event, many of the hospital's costs will have already been incurred. For example, the operating room will have been occupied during the start of the procedure and must still be prepared for the next patient. Similarly, sterile supplies will have been opened and will either be disposed of or be reprocessed at additional cost.

The IHA believes that before CMS establishes reductions in payments for procedures billed using these modifiers, there must be evidence supporting the need for payment reductions and the level of reductions that would be applied.

Physician Oversight of Nonphysician Practitioners

The IHA supports CMS's proposal to defer to State law regarding the need for physicians to review and sign the medical records for outpatients cared for by nonphysician practitioners in critical access hospitals (CAHs). However, we would also recommend that CMS extend the application of this policy to apply to physician review of inpatient records for patients cared for by nonphysician practitioners. If state law permits these practitioners to practice independently, CMS should not require physician oversight in either the outpatient or inpatient setting. We agree that State laws providing independent practice authority generate sufficient control and oversight of these nonphysician practitioners and we do not believe that quality of care is reduced by nonphysician practitioners

The IHA also supports the additional flexibility CMS adds under this proposed policy for those states that do not allow for independent practice of nonphysician practitioners – in particular permitting the facility to establish policy regarding the sample size of outpatient records to be reviewed and signed, consistent with current standards of practice.

IDAHO HOSPITAL
ASSOCIATION

September 14, 2005

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, S.W.
Room 445-G
Washington, DC 20201

Ref: [CMS-1501-P] Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System (OPPS) and Calendar Year 2006 Payment Rates (70 *Federal Register* 42673), July 25, 2005.

Dear Dr. McClellan:

On behalf of our 44 member hospitals, the Idaho Hospital Association (IHA) appreciates this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule establishing new policies and payment rates for hospital outpatient services for calendar year 2006.

Our analysis of the proposed rule indicates that many ambulatory payment classification (APC) rates continue to fluctuate dramatically, with payments much lower or higher in 2006 than in 2005. These changes make it extremely difficult for hospitals to plan and budget from year to year. Among these "broken" APCs, several of the evaluation and management (E/M) services APCs – and especially clinic visits -- continue to experience declines in payment rates. We would expect that four years after the start of the OPPS, the payment rates and associated payment-to-cost ratios would be much more stable.

Further, the entire OPPS is underfunded, paying only 87 cents for every dollar of hospital outpatient care provided to Medicare beneficiaries. Hospitals must have adequate funds to address critical issues like severe worker shortages, skyrocketing liability premiums, expensive drugs and technologies, aging facilities, expensive regulatory mandates and more. **The IHA will continue to work with our members Congress to address inadequate payment rates and updates in order to ensure access to hospital-based outpatient services for Medicare beneficiaries.**

CANCER DATA
REGISTRY OF IDAHO

GROUP UNEMPLOYMENT
COMPENSATION PROGRAM

P. O. BOX 1278
BOISE, ID 83701-1278
PHONE: 208.338.5100
FAX: 208.338.7800

IDAHO HOSPITAL
ASSOCIATION

The proposed rule contains a number of significant policy changes, including changes to payments for handling costs hospital incur for separately paid drugs, increases in the threshold for the outlier policy, reduced payments for multiple imaging procedures, and changes to payment for rural hospitals. We address these areas briefly in our cover letter and attach detailed comments on these and other issues.

Pharmacy Overhead and Drug Handling Payment Rate Adjustment

The proposed rule adjusts the APC rates for separately payable drugs to take into account pharmacy overhead and drug handling costs. Since CMS does not have separate hospital charge data on these pharmacy costs, in 2006 the agency proposes to pay 2 percent of the average sales price (ASP) for these products. To set payment rates in the future, CMS proposes three distinct temporary HCPCS codes (C-codes) and corresponding APCs to differentiate by level of overhead costs for drugs and biologicals. Hospitals would be instructed to charge the appropriate pharmacy overhead C-code when they provide separately payable drugs.

The IHA believes that handling costs for drugs and biologicals delivered in the hospital outpatient department are significant and should be reimbursed by Medicare. The ASP+2 percent adjustment is an appropriate temporary measure. However, we have serious operational concerns about the requirement that hospitals establish separate charges for pharmacy overhead using the three proposed C-codes. Most importantly, Medicare providers must have uniform charges for all payers, but payers other than Medicare do not use the C-codes. If implemented, this policy would require hospitals to break the law by having two charges for their drugs –- one for Medicare that does not include handling costs and one for other payers that does.

For this and many other reasons outlined in our detailed comments, the **IHA is strongly opposed to CMS' proposal to require hospitals to establish separate charges for pharmacy overhead for separately payable drugs using the three proposed C-codes.** Instead, we recommend that CMS work with stakeholder groups to collect further data and develop alternative and simpler solutions. The AHA has volunteered to convene a group of member hospitals to discuss possible alternatives. If CMS decides to proceed with implementing this burdensome drug handling C-codes policy, the IHA strongly suggests a grace period of no less than 6 months to allow hospitals to make system changes and train staff.

Outlier policy

The IHA also continues to be concerned about the outlier policy. The proposed rule would decrease the set aside for outlier payments from 2 to 1 percent and increase the dollar threshold for receiving outlier payments by $400, to $1,575. We are concerned about whether the proposed threshold is too high and request clarification on how it was determined. In addition, as in previous years, the proposed rule does not include data on the actual outlier payments made in 2005 and prior years. **Therefore, the IHA strongly recommends**

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that in the final rule CMS publish data on actual outlier payments made in 2004 and prior years and that actual outlier payments for 2005 and later years be reported as soon as possible.

Reduced payment for multiple imaging procedures

CMS proposes reducing payment when multiple imaging services are provided on the same day, with full payment for the highest paid imaging service and a 50 percent reduction in payment for additional procedures from the same "family" of procedures performed in the same session. The proposed rule outlines 11 "families" of imaging procedures by imaging modality and by contiguous body area. In developing this policy, CMS did not examine hospital cost data. Rather, the agency relied on Medicare physician fee schedule practice expense data for determining the level of the discount. No evidence has been presented to justify the reduction in payment or to suggest that the 50 percent discount represents the right level of efficiencies obtained by hospitals, if they even exist.

The IHA opposes moving forward with this policy without a better justification and more substantial, hospital-based data to support the policy. We would note that the APC advisory panel came to the same conclusion. We are also concerned the lack of implementation detail provided in the proposed rule. For example, what exactly is meant by "the same session?" Finally, we would like clarification on how exactly CMS would ensure that this change is budget neutral. The proposed rule provides no detail on how the impact of the multiple imaging procedures discount was calculated or how the budget neutrality factor was adjusted.

Changes to payments for rural hospitals

The proposed rule announces the expiration of hold-harmless payments for small rural hospitals. These are vulnerable facilities that provide important access to care for populations in their communities. The AHA is working with members of Congress on legislation that will permanently extend hold harmless payments to small rural hospitals and rural sole community hospitals, as is currently the case for cancer hospitals and children's hospitals.

The proposed rule also presents the findings of a study on rural versus urban hospital outpatient costs, and concludes that a 6.6 percent payment increase is needed for rural sole community hospitals (SCHs). The AHA is concerned that the supporting analysis in Table 6 of the proposed rule does not separately present findings for rural hospitals with 100 or fewer beds that are not rural SCHs. **We urge CMS to present its findings for rural hospitals with 100 or fewer beds that are not SCHs or explain why they cannot report these results.** The AHA also seeks clarification on whether the 6.6 percent payment increase is affected by hospital reclassifications or participation in the Rural Community Hospital (RCH) demonstration program.

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ASSOCIATION

We attach detailed comments on the proposed changes to the OPPS. In them, we expand on the points raised above and also address the following: the calculation of 2005 rates and weights, partial hospitalization services, new technology applications, hyperbaric oxygen, drug administration, evaluation and management services, blood and blood products, inpatient-only procedures, ancillary outpatient services, and physician oversight of non-physician practitioners.

The IHA appreciates the opportunity to comment. If you have any questions please feel free to contact me at (208) 338-5100 x209.

Sincerely,

Carla Terry
Vice President Finance
Attachment

CDRI
CANCER DATA
REGISTRY OF IDAHO

GUCP
GROUP UNEMPLOYMENT
COMPENSATION PROGRAM

P. O. BOX 1278
BOISE, ID 83701-1278
PHONE: 208.338.5100
FAX: 208.338.7800

Submitter : Dr. Nathan Painter **Date:** 09/14/2005

Organization : Loma Linda University, School of Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

This reimbursement formula is inadequate to cover handling costs of drugs. Small hospitals, particularly, may be forced to limit or eliminate the treatment of patients in outpatient settings and ambulatory care clinics may have to close their in house pharmacies. The ramifications of instituting this formula will be disastrous. The places and processes of providing services will change - to the detriment of patients who will not receive treatment by their providers of choice. Inadequate reimbursement to hospital outpatient departments will impact the quality, safety and level of their services.

Submitter : Ms. M.B. Schuh **Date: 09/14/2005**

Organization : St. Anthony's Medical Center

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

I was disappointed that CMS failed to address, as it has in other proposed rules, the decision that unlisted procedures codes are assigned to the lowest level, clinically appropriate APC group. Has CMS examined claims data to try to match unlisted procedure codes to diagnoses to determine whether there may be a more appropriate APC classification for a procedure that cannot be classified to an existing HCPCS code? I believe the assignment of unlisted HCPCS codes should have been addressed in the proposed rule in order to open the issue for public comment.

Submitter : Mrs. Lisa McCloud **Date: 09/14/2005**

Organization : Thomas Wound Care Center

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

? Proposed rule CMS-1501-P ?Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates? contains errors which would seriously undermine wound care in the United States

? Apligraf is an advance bioengineered tissue based therapy indicated for treatment of venous leg ulcers and diabetic foot ulcers. It is an important element of advanced wound care, shown to speed up healing rates and reduce amputations in severely affected patients. It is the only tissue based therapy approved for treatment of venous leg ulcers.

? Apligraf and Dermagraft are currently reimbursed in the hospital prospective payment system as a specified covered drug

? Although the proposed rule is intended to provide reimbursement of ASP+8% for covered products, in the case of Apligraf and Dermagraft, the reimbursement rate is proposed to be 30% below the selling price of the product.

Apligraf -- 2005 outpatient rate $1,130.88; 2006 proposed outpatient rate $766.84

Dermagraft -- 2005 outpatient rate $529.54; 2006 proposed outpatient rate $368.32

? Reimbursement at this rate would jeopardize patient access to Apligraf and Dermagraft and that would have a very negative impact on quality of care.

? We petition CMS to correct the error in the proposed ruling and ensure that Apligraf and Dermagraft are reimbursed as a specified covered drug, at ASP+8%.

Submitter : **Date: 09/14/2005**

Organization :

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

comment here

Submitter : **Dr. John Lund** **Date: 09/14/2005**

Organization : **Intermountain Health Care**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

As a major health care provider in our area, we implant medical devices and perform other procedures on a number of Medicare beneficiaries in the outpatient setting. I am writing to express my concerns about the proposed Outpatient Payment rule for calendar Year 2006.

In the proposed rule, CMS recommends a decrease of 14.1% from last year?s rate for ICD devices. Payment decreases of 14% from one year to the next are problematic on their face and can not be justified, particularly when the 2005 rates show a 2.3% reduction from the year before. No aspect of health care has dropped that much in two years. The resulting APC rates are actually lower than our institution?s cost for the ICD device, leaving us with a loss for the device acquisition cost and no payment for our procedural costs. These losses make it very difficult for us to continue to offer device implant procedures in the outpatient hospital setting.

To rectify this issue, our facility requests that CMS calculate the 2006 payment rates for ICD implant procedures using the 2005 payment rates plus the 3.2% hospital update. I understand that the August 2005 APC Advisory Panel has made the same recommendation to CMS. The resulting payment rates would be more in line with our facility?s costs of performing these services.

CMS also requested comments on the February 2005 APC Advisory Panel recommendations related to increasing the single procedure bills available for rate setting to improve the accuracy of median costs for APCs 0107 (ICD generator replacement) and 0108 (full system implant). Although the scenarios displayed in the proposed rule may increase the number of single procedure claims used for rate setting, single procedure claims have not resulted in adequate payment. We are therefore unable to support the proposal.

For 2006, CMS is proposing to move the left ventricular lead implant associated with cardiac resynchronization pacing and defibrillation systems (CPT 33225) from APC 1525 to APC 0418, resulting in a change in the status indicator. The status indicator would change from a status "S" meaning that it was always paid at 100% of the APC payment rate, to a status "T" which means that it is subject to a 50% reduction in multiple procedure scenarios.

The assignment of status indicator ?T? does not adequately compensate hospitals for additional procedural time and resources associated with this service. The implant procedure for the cardiac resynchronization pacing and defibrillator systems parallel that of a conventional dual chamber pacemaker or ICD with the exception of the implantation of a left ventricular lead and is not duplicative. The cost of the lead itself is not reduced by 50% when implanted along with other procedures. Please do not change the status indicator for this procedure.

Thank you for this opportunity to provide comments.

Sincerely,

John F. Lund MD
McKay-Dee Cardiology
McKay-Dee Hospital Center

Submitter : **Dr. Anne Curtis** **Date: 09/14/2005**

Organization : **Heart Rhythm Society**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Also as an attachment

Mark McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
P.O. Box 8016
Baltimore, MD 21244-8018

Dear Dr. McClellan:

Re: Medicare proposed device reimbursement in hospital outpatient payments for 2006.

The Heart Rhythm Society (HRS) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) Proposed Rule on the Medicare Hospital Outpatient Prospective Payment System (OPPS) for FY 2006, published in the July 25 , 2005 Federal Register (CMS-1501-P). The Heart Rhythm Society is the international leader in science, education and advocacy for cardiac arrhythmia professionals and patients and the primary information resource on heart rhythm disorders.

?Device Related APCs?
The Heart Rhythm Society is very concerned with the proposed reductions for device related procedures, specifically for implantable cardioverter defibrillators (ICDs). The Heart Rhythm Society believes it is a requirement of any payment system to appropriately pay for medical services so as not to limit access to care or diminish the quality of care. The proposed reductions for ICDs are based on inaccurate and incomplete data. CMS acknowledged at the meeting of the Advisory Panel on APC Groups held August 17, 18, 2005 that the data used as a basis for this proposed rule ?may not be accurate or complete?.

The 2006 OPPS proposed rule payment rates for ambulatory payment classification (APC) groups 0107 Implantation of Cardioverter-Defibrillator and 0108 Insertion/Replacement/Repair of Cardioverter Defibrillator Leads and Insertion of Cardioverter-Defibrillator, mark the second consecutive year of payment decreases amounting to -16.8%. The proposed rates will not cover the hospital?s cost of the ICD and additional procedural costs.

ICDs have been shown in many clinical trials to save lives and reduce the enormous loss of life due to sudden cardiac arrest. The impact of a payment decrease of this magnitude will affect patient access to care. Given this unprecedented payment reduction, there will likely be no expansion of the availability of this life-saving clinical technology, as hospitals will not be able to absorb the losses associated with the implementation of a device implant program. As such, access to life-saving implantable defibrillation technology will become limited.

Recommendation
The CMS Advisory Panel recommended CMS create adequate payment levels for ICD procedures by using 100% of the 2005 payment rates plus the hospital update of 3.2% to create the 2006 final OPPS payment rates for APCs 0107 and 0108. The Heart Rhythm Society fully supports this recommendation and strongly encourages CMS to implement the 2006 final OPPS with this recommendation. If CMS staff have questions please feel free to contact Brian Outland, Manager of Regulatory and Reimbursement Affairs at boutland@HRSonline.org or 202-464-3433.

Sincerely,

Anne B. Curtis, MD
President, Heart Rhythm Society

Mark D. Carlson, MD
Chair ? Health Policy Committee

CMS-1501-P-408-Attach-1.DOC

Submitter : Mr. Michael O'Laughlin **Date:** 09/14/2005

Organization : Mercy Health Center, Ft.Scott, Ks

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Regarding proposed payment changes for blood products. At our facility we have seen a 6% increase in charges from American Red Cross on on products we receive from them in the last year. I don't see any reductions in the Red Cross fee schedule in the future and your proposed reductions will be a hardship for us. As the laboratory director of a small, rural hospital, I can tell you this is a difficult burden for us to bear.

Submitter : **Mrs. Patricia Epple** **Date: 09/14/2005**

Organization : **Pennsylvania Pharmacists Association**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

The Pennsylvania Pharmacists Association has some serious concerns regarding the proposed payment rates.

We strongly believe that this reimbursement formula is inadequate to cover handling costs of drugs. Small hospitals, in particular, may be forced to limit or eliminate the treatment of patients in outpatient settings. This along could cause serious problems. The ramifications of instituting this formula will be disastrous. The places and processes of providing services will change - to the detriment of patients who will not receive treatment by their providers of choice. Inadequate reimbursement to hospital outpatient departments will impact the quality, safety and level of their services.

We believe that the proposal being made by the Association of Community Cancer Centers (ACCC) to consider an allowance of 8% to cover pharmacy handling and overhead expenses for all drugs reimbursed under the hospital OPPS, in addition to ASP + 6% to cover the drug acquisition cost, would be a better alternative.

We strongly urge that CMS conduct some type of study/report which would collect hospital charge data for overhead costs for two years to determine if even this 8% rate is adequate and to also then consider new reimbursement rates for these costs for payment in 2008.

We appreciate your consideration of these concerns.

The Academy of Health-System Pharmacists
Pennsylvania Pharmacists Association

Submitter : **Miss. Dawn Day** **Date: 09/14/2005**

Organization : **Mercy Wound Care Center**

Category : **Nurse Practitioner**

Issue Areas/Comments

GENERAL

GENERAL

Please correct the 2006 reimbursement for Apligraf and Dermagraft. We have used these products to heal venous statis ulcers and diabetic ulcers quickly. We want to ensure that these products are available for our patients next year.

Submitter : **Mrs. Valerie Dalton** **Date: 09/14/2005**

Organization : **Synergy Healthcare Group**

Category : **Other Health Care Provider**

Issue Areas/Comments

GENERAL

GENERAL

To: CMS
From: Valerie Dalton, RN
Synergy Healthcare Group, Inc.
Date: September 14, 2005
Re: CMS -1501-P 2006 Proposed Payment Rate

COMMENTS TO PROPOSED RULE

Synergy Healthcare Group provides mental health services to over 500 patients a year in four Partial Hospitalization Programs located in Slidell, New Orleans, Baton Rouge Louisiana and Biloxi Mississippi. The patients that we service are the chronically mental ill treated in an outpatient setting.

The proposed 15% reduction in reimbursement for partial hospitalization programs (PHP) will require most PHP?s to either drastically reduce the services provided or go out of business. We are currently reimbursed an average of $250 per day per patient. Medicare reimburses 80% or $200 and the remaining 20% is a co-pay expected to be paid by the patient. Since the patients are chronically mental ill individuals the majority are unable to work and thus unable to pay the 20% co-pay; 99% of the co-pay?s are bad debt write-offs. The 15% reduction will reduce our actual reimbursement from $200 to approximately $175 per day.

Approximately 75% of our patients are patients discharged from inpatient psychiatric hospitals and come to PHP in lieu of continued hospitalization. These patients are high acuity patients who often have inadequate resources for continued recovery without the assistance of PHP. Many, for example, do not have financial resources to pay for medications which are often absorbed by the PHP in an effort to stabilize the patient post-hospital.

A partial hospitalization program day consist of at least four therapy groups a day, the facility must also provide lunch and snacks and travel to and from the facility. It will be extremely difficult if not impossible to provide the services needed for these patients if the 15% reduction in reimbursement is approved. PHP?s play a big role in the community whereby if these patients are not receiving treatment they most likely will end up either institutionalized, living on the streets or imprisoned.

Sincerely,

Valerie Dalton, RN
COO

Submitter : **Mr. Phil Martin** **Date: 09/14/2005**

Organization : **Salem Hospital - Home Infusion - SHAPES**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

This reimbursement formula is inadequate to cover handling costs of drugs. Outpatient IV infusion services are expected to accept reimbursement as if a bottle of pills were dispensed. Infusion centers provide labor intensive admixture services, compounding sterile IV products in a regulatory required sterile environment. Outpatient infusion centers may be forced to limit or eliminate the treatment of patients in outpatient settings. The ramifications of instituting this formula will be disastrous. The places and processes of providing services will change - to the detriment of patients who will not receive treatment by their providers of choice. Inadequate reimbursement to hospital outpatient departments will impact the quality, safety and level of their services.

Submitter : **Dr. Jeffrey Niezgoda** **Date: 09/14/2005**

Organization : **ACHM / UHMS**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Re: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; Proposed Rule
File Code: CMS ? 1505 ? P
Proposed Payments for Drugs, Biologicals, and Radiopharmaceuticals Without
Pass-Through Status

September 10th, 2005

Dear Dr. McClellan:

I am a hyperbaric and wound care physician, devoting 100% of my clinical time to the treatment of patients with compromised wounds. In addition, I am the Vice President of the American College of Hyperbaric Medicine (ACHM) and the Chairman of the Wound Care Liaison Committee of the Undersea and Hyperbaric Medical Society (UHMS). In these roles, I represent hundreds of physician hyperbaric and wound care specialists.

I am writing this letter to address concerns related to the Centers for Medicare and Medicaid Services Proposed Rule published in the July 25th, 2005, Federal Register entitled, "Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates.? Specifically, I would like to direct attention to the proposed revision regarding payment for bioengineered human tissue substitutes - Apligraf (C 1305) and Dermagraft (C 9201).

Apligraf and Dermagraft are advanced wound care technologies that employ living human cells in the treatment of patients with compromised and chronic wounds. These skin substitutes allow improved outcomes as evidenced by hastened wound healing and prevention of limb loss in select patients. Previously, both Apligraf and Dermagraft were paid as biologics and had been covered through the hospital outpatient prospective payment system as specified outpatient drugs. In the proposed 2006 Medicare Hospital Outpatient Rule, CMS plans to reimburse covered outpatient drugs at average sales price [ASP] + 6 percent of the acquisition cost of the drug. The proposed rule change and payment is inaccurate for both Apligraf and Dermagraft as this is based on 2004 claims data instead the ASP. Based on this inaccuracy, the decrease in payment is so severe that it would likely not allow for continued Apligraf or Dermagraph utilization in a clinical setting. This translates to increased risk to the Medicare beneficiary who would not have access to either of these technologies.

Apligraf 2005 hospital outpatient payment = $ 1,130.88
2006 proposed hospital outpatient payment = $ 766.84

Dermagraft 2005 hospital outpatient payment = $ 529.54
2006 proposed hospital outpatient payment = $ 368.32

On behalf of the physician membership of the ACHM and the UHMS, I respectfully request that this issue be reevaluated and that the proposed 2006 Medicare hospital outpatient reimbursement for Apligraf and Dermagraft be reconsidered.

Sincerely,

Jeffrey A. Niezgoda, MD, FACHM, FACEP
Medical Director
Center for Comprehensive Wound Care and
Hyperbaric Oxygen Therapy
Aurora Health Care
2901 W KK Pkwy, Suite 311
Milwaukee, WI 53215
Office (414) 385-8723
Pager (414) 222-1235
Mobile (414) 510-2900

Submitter : Michele DeSmet **Date:** 09/14/2005

Organization : Oakwood Healthcare, Inc.

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-415-Attach-1.DOC

CMS-1501-P-415-Attach-2.DOC

September 14, 2005

Centers for Medicare and Medicaid Services
Department for Health and Human Services
Attn: CMS 1500-P
PO Box 8011
Baltimore, MD 21244-1850

Re: **CMS-1501-P**
Medicare Program; Changes to the Outpatient Prospective Payment System and 2006 Rates; Proposed Rule, July 25, 2005 *Federal Register*

Dear Dr. McClellan:

Oakwood Healthcare, Inc. welcomes this opportunity to comment on the proposed rule promulgated by the Centers for Medicare and Medicaid Services ("CMS") regarding the Medicare Outpatient Prospective Payment System for calendar year 2006, as published in the July 25, 2005 *Federal Register*. Oakwood Healthcare, Inc., located in Dearborn, Michigan, operates four not-for profit acute care hospitals with 1,307 licensed beds.

HOSPITAL MARKET BASKET INCREASE

(*Federal Register Page 42694-42695)*

The hospital update is based on a "marketbasket" factor that is intended to reflect the average change in the price of goods and services hospitals purchase to furnish patient care. These price changes must be projected forward to estimate increases for the subsequent year so that an appropriate marketbasket update can be determined in advance of payment. The payment system is prospective, and the update is not retroactively reconciled to reflect actual price increases for the year. Therefore, a reliable projection methodology is vital to ensure equitable payments.

For the hospital inpatient PPS, the FY 2006 inpatient proposed rule included a 3.2 percent update, with the actual increase in the final rule set at 3.7 percent, based upon a change in methodology. **Oakwood Healthcare, Inc. requests that the CMS revise the marketbasket update included in the final OPPS rule to include a 3.7 percent marketbasket update, consistent with the inpatient final rule.**

COST OUTLIER PAYMENT THRESHOLDS

(*Federal Register* pages 42701- 42702)

The CMS provides outlier payments for individual services or procedures with extraordinarily high costs compared to the payment rates of the APC group. For the 2005 OPPS, outlier payments are made for services with costs that exceed 1.75 times the APC payment rate and the APC rate plus a $1,175 fixed-dollar threshold. This dual test was intended to eliminate outlier payments for low-cost services and provide higher outlier payments for more expensive procedures.

Since implementation of the OPPS in August 2000, the CMS has set aside a targeted outlier payment pool of 2.0 percent of total OPPS payments. In the proposed rule, the CMS cited the Medicare Payment Advisory Commission's (MedPAC) March 2004 report, which suggests Congress should eliminate the outlier policy under the OPPS. The CMS states that, although elimination of outlier payments would require a statutory change, many of the reasons cited by MedPAC justify a reduction in the size of the outlier payment pool.

For 2006, the CMS is proposing to set a projected target for aggregate outlier payments at 1.0 percent of aggregate total payments under the OPPS. In order to ensure that estimated 2006 aggregate outlier payments would equal 1.0 percent of estimated aggregate total payments under OPPS, the CMS is proposing that the outlier threshold be modified so that outlier payments are made when the cost of furnishing a service or procedure by a hospital exceeds 1.75 times the APC payment amount and exceeds the APC payment rate plus a $1,575 fixed dollar threshold, which is $400 more than the current threshold. The CMS will continue to pay 50 percent of the amount by which the cost of furnishing the service exceeds 1.75 times the APC payment rate when the cost of a hospital outpatient service exceeds these thresholds. The proposed change to reduce the outlier pool by 1 percent will be implemented in a budget-neutral manner by increasing the APC conversion factor by 1 percent.

Oakwood Healthcare, Inc. is concerned about the re-distributional impact of this change, which we believe is inappropriate. In the inpatient final rule, the CMS indicated its charge estimate was too high, and lowered the threshold considerably in the final rule. If the CMS is using the same charge estimates for purposes of the OPPS proposed rule, then the agency should make a similar adjustment to the methodology used to calculate the threshold in the OPPS final rule. In addition, for the past four years, the CMS set aside two percent of total estimated OPPS payments to fund hospital outlier payments. For 2006, the CMS is proposing to set aside only one percent for outlier payments. However, the agency does not publicly release data regarding how much of the established outlier pool was actually spent in prior years in the *Federal Register* or on its website. Due to the significant changes to outlier policies proposed for 2006, Oakwood Healthcare, Inc. is concerned that Medicare may not actually spend the entire one percent pool. Therefore, **we strongly recommend that in the final rule, the CMS publish data regarding actual outlier payments made in 2004 and prior years, and to report this data in the future.** We also seek further clarification from the CMS regarding how the $1,575 fixed dollar threshold was calculated. In addition, we **urge the CMS to maintain the outlier threshold at the current level and to maintain the total outlier pool at the current 2.0 of aggregate OPPS payments.**

MULTIPLE DIAGNOSTIC IMAGING PROCEDURES

(Federal Register pages 42748 - 42751)

Currently, hospitals receive a full APC payment for each diagnostic imaging procedure on a claim, regardless of how many procedures are performed using a single imaging modality and whether or not contiguous areas of the body are studied during the same encounter.

In its March 2005 Report to Congress, MedPAC recommended improved Medicare coding edits that would detect unbundled diagnostic imaging services and reduce the technical component payment for multiple imaging services when they are performed on contiguous areas of the body. Currently, payment rates are based on each service being provided independently and the rates do not account for efficiencies that may be gained when multiple studies using the same imaging modality are performed in the same session. For surgical procedures, the OPPS has a longstanding policy of reducing payment for multiple procedures performed on the same patient during the same operative session. In such cases, full payment is made for the procedure with the highest APC payment rate, and each subsequent procedure is paid at 50 percent of its respective APC payment rate.

For 2006, the CMS is proposing to pay 100 percent for the diagnostic imaging procedure with the highest APC payment rate, and pay only 50-percent for each additional imaging procedure when all the procedures are performed during a single patient encounter and all are within an identified "family" of procedures that are commonly billed on the same day. The CMS identified 11 "families" of imaging procedures by imaging modality and by contiguous body area. The agency is proposing to apply the multiple imaging procedure reduction to individual services described by codes within one Family, not across Families. For example, no reduction would apply to an MRI of the brain (CPT code 70552) in code Family 5, when performed in the same session as an MRI of the spinal canal and contents (CPT code 72142) in code Family 6. The CMS is proposing to make full payment for the procedure with the highest APC payment rate, and payment at 50 percent of the applicable APC payment rate for each additional procedure, when performed in the same session. In developing this policy, the CMS did not examine hospital cost data but relied on Medicare physician fee schedule practice expense data for determining the discount level. No evidence has been presented to justify the reduction in payment or to suggest that the 50 percent discount represents the appropriate level of efficiencies obtained by hospitals, if they even exist.

Oakwood Healthcare, Inc. opposes moving forward with this policy without solid justification, and more substantial, hospital-based data to support the policy. We note that the APC Advisory panel came to the same conclusion. Additional concerns include:

- how this policy would be applied; use of the Medicare physician fee schedule practice expense data for determining the level of the discount;
- the policy lacks detail and justification for the 50 percent discount;
- how the CMS would define the "same session". In some circumstances a patient may have a procedure performed earlier in the day and subsequently on the same day have another procedure that may fall within the same family and incorrectly be subject to the discount.

- how the CMS would ensure that this change is budget neutral.

PHARMACY OVERHEAD & DRUG HANDLING – PAYMENT RATE ADJUSTMENT
(Federal Register pages 42728 – 42731)

The MMA required MedPAC to submit a report to the HHS Secretary on adjusting the APC rates for specified covered outpatient drugs, taking into account overhead and related expenses, such as pharmacy services and handling costs. The provision required a recommendation as to whether payment adjustment should be made; and the methodology for adjusting payment, if an adjustment is recommended. MedPAC concluded that the handling costs for drugs, biologicals, and radiopharmaceuticals delivered in the hospital outpatient setting are significant, as medications administered in outpatient departments generally require greater pharmacy preparation time that those provided in the inpatient setting.

For 2006, the CMS did not propose to create separate handling categories for radiopharmaceutical agents. However, for drugs and biologicals, the CMS proposes to establish three distinct HCPCS C-codes and corresponding APCs for drug handling categories to differentiate overhead costs for drugs and biologicals and instruct hospitals to charge the appropriate pharmacy overhead C-code for overhead costs associated with administration of each separately payable drug and biological based on the code description that best reflects the service required by the hospital in preparing the pharmaceutical product for administering to a patient. Since the CMS does not have separate hospital charge data for pharmacy overhead, for 2006, they propose to pay for these costs based on two percent of the Average Sales Price (ASP). This would result in overall drug payments, including the drug itself and the associated handling payment, of ASP + 8 percent which is a rate that the CMS states is equivalent, on average, to the mean cost for drugs derived from hospital claims data.

Oakwood Healthcare, Inc. agrees with the MedPAC finding that handling costs for drugs and biologicals delivered in the hospital outpatient department are significant and should be reimbursed by Medicare. We believe that, while imperfect, the ASP + 2 percent adjustment for drug handling would be appropriate as a temporary measure. In the future, the CMS should work with hospital and pharmacy stakeholders to develop an approach to establish differential add-on payments for drug handling costs to account for a wide variety of drug handling categories.

Oakwood Healthcare, Inc. is strongly opposed to the CMS' proposal to require hospitals to establish separate charges for pharmacy overhead for separately payable drugs and biologicals and to utilize the three proposed C-codes for charging these overhead costs. This would be extremely burdensome for hospitals to implement. There are many complex issues and administratively burdensome aspects to adopting the CMS proposal for charging drug handling through the use of these new C-codes. These issues include:

- Hospitals will have to evaluate the normal mark-up formula for all pharmacy items and pull out the handling costs for some, but not all, of these drugs and biologicals. That is, hospitals would have to identify and strip out the handling charges for

separately payable drugs under Medicare while the drug handling charges for packaged drugs would remain incorporated within the overall charge for the drug.

- For each separately payable drug, hospitals will need to assign the handling charge to one of the CMS' proposed new drug handling C-codes. These codes are only recognized by and acceptable to Medicare, but not other payers. Hospitals will therefore have to modify their billing systems to separate out the drug handling from the drug charge for Medicare claims but bill them as a single line item for other payers. This may be impossible for hospitals to implement as they have uniform charging policies for all payors. In addition, drug pricing is generated via a pharmacy charging system that is often outside the hospital's normal charging system and may not be able to accommodate the CMS proposed C-codes.
- There is confusion regarding how the handling C-codes would apply when a hospital pharmacy mixes multiple doses of a drug for a patient.
- Many hospitals use the same charge master for inpatient and outpatient services. If the handling charge must be separated out of the drug charge for the outpatient setting, there are questions regarding how the CMS will expect providers to report drug charges in the inpatient setting versus the outpatient setting.

Oakwood Healthcare, Inc. strongly opposes this expansion of the drug handling C-coding proposal to packaged drugs. This would exponentially increase the coding and administrative burden on hospitals due to the sheer number of drugs that would require special charging practices for Medicare purposes. In addition, we strongly recommend that the CMS does not implement the proposed drug handling C-codes in 2006, but we suggest that the CMS work with stakeholder groups to collect further data and develop alternative and simplified solutions for ensuring that hospitals are appropriately paid for their pharmacy overhead and drug handling costs and the CMS obtains the information that it desires. If the CMS decides to proceed with implementing this burdensome drug-handling C-does policy, then Oakwood Healthcare, Inc. strongly suggests that the CMS provide a grace period of no less than 90 days after implementation of the 2006 OPPS, or until April 1, 2006, to allow hospitals to make necessary system changes, educate pharmacy staff, finance staff and coders on the required use of the drug handling "C" codes.

INPATIENT ONLY PROCEDURES LISTING
(Federal Register pages 42745 – 42746)

The CMS proposes to remove 25 codes from the "inpatient only" listing—a listing that identifies services for which Medicare does not provide payment if they are performed in an outpatient setting and assigns them to clinically appropriate APCs.

Oakwood Healthcare, Inc. continues to urge that the CMS entirely eliminate the "inpatient only" list, which undermines clinical decision-making. Physicians, not hospitals, determine where procedures can be safely performed, as well as whether a patient's medical condition warrants an inpatient admission. If a physician determines that a service can be safely performed in an outpatient setting, under current rules, the hospital is penalized if that procedure is on the

"inpatient only" listing. If the "inpatient only" list is not eliminated for 2006, the CMS should consider establishing an appeals process to address circumstances in which payment for a service provided on an outpatient basis is denied because it is on the "inpatient only" list. This would allow the provider an opportunity to submit documentation to appeal the denial, such as physician's intent, patient's clinical condition, and the circumstances that allowed the patient to safely be sent home without an inpatient admission.

APC RELATIVE WEIGHTS
(Federal Register pages 42680 – 42692)

While Oakwood Healthcare, Inc. continues to support the use of the most recent claims and cost report data and the inclusion of multi-procedure claims, we request that the CMS provide a public use file that would indicate the impact of each individual proposed methodology change. This would allow health care providers to review the file and determine the specific impact on their own operations while also providing a stronger, more solid basis for helpful comments to the CMS.

PARTIAL HOSPITALIZATION
(Federal Register pages 42692 – 42694)

Oakwood Healthcare, Inc. is concerned that the 15 percent reduction in the per diem payment rate for partial hospitalization services that the CMS proposed for 2006 could have serious negative consequences on the financial viability of partial hospitalization services in hospitals and health care systems which could endanger Medicare beneficiary access to these vital services. This is particularly concerning since these services are already vulnerable, with many programs closing or drastically limiting the number of patients accepted during recent years.

While we recognize the CMS's proposal was made in order to avoid an even more significant reduction in the payment rate for these services, we do not believe that hospitals that offer partial hospitalization services should be penalized for the instability in data reporting that stems from community mental health center (CMHC) based services. Instead, we recommend in the final rule for 2006, the CMS freeze payment rates for partial hospitalization services at the 2005 levels. This approach will provide for payment stability for these services while protecting beneficiary access and allowing the CMS adequate time to address the instability in the CMHC data.

BLOOD & BLOOD PRODUCTS
(Federal Register pages 42740 – 42742)

The CMS proposes to continue making separate payments for blood and blood products through individual APCs for each product. The agency also proposes to establish payment rates for blood and blood products based on their 2004 claims data, utilizing an actual or simulated hospital blood-specific cost-to-charge ratio to convert charges to costs for blood and blood products. For blood and blood products whose 2006 simulated medians would experience a

decrease of more than 10 percent in comparison to their 2005 payment medians, the CMS is proposing to limit the decrease in medians to 10 percent.

While this approach results in modest payment increases for many blood and blood product APCs, the payment rate for leukocyte-reduced red blood cells (APC 0954), the most commonly transfused blood product, and rates for certain other blood and blood product APCs will continue to decline under this methodology. According to data from the American Association of Blood Banks, the proposed rate for several of these blood products is significantly below hospitals' actual acquisition cost for blood, most notably for leukocyte-reduced red blood cells, and, with the introduction of additional blood safety measures, it is likely that the cost of these products will continue to increase, making the proposed Medicare payment rate even more inadequate.

To ensure continued beneficiary access to all blood and blood products, Oakwood Healthcare, Inc. recommends that CMS set 2006 rates at *the greater of*: (1) the simulated medians calculated using the 2004 claims data; or (2) the 2005 APC payment medians for these products.

OBSERVATION SERVICES
(Federal Register pages 42742 – 42745)

Currently, Medicare provides a separate observation care payment for patients with congestive heart failure (CHF), chest pain, and asthma. In order to reduce administrative burden on hospitals when attempting to differentiate between packaged and separately payable observation services, the CMS proposes to discontinue current HCPCS codes for observation services (G0244, G0263, and G0264) and instead create two new HCPCS codes to be used by hospitals to report all observation services: GXXXX (Hospital observation services, per hour) and GYYYY (Direct admission of patient for hospital observation care). The CMS would shift determination of whether or not observation services are separately payable under APC 0339 from the hospital billing department to the outpatient PPS claims processing logic contained in the Outpatient Code Editor (OCE) system.

Oakwood Healthcare, Inc. supports the concept of allowing the OCE logic to determine whether services are separately payable as this will result in a simpler and less burdensome process for ensuring payment for the provision of covered outpatient observation services. The existing G codes for observation services, with their long, complex descriptors that encompassed all variables required for claim processing into a single code, create a significant administrative burden for hospital coders and billers. We are pleased that CMS has found a method to reduce the burden by simplifying the G codes required for observation services and making changes to the OCE logic.

However, we believe that the OCE logic could be used even more efficiently by making the HCPCS code GYYYY (Direct admission of patient for hospital observation care) unnecessary. If the hospital bills the GXXXX code and the claim *does not* include a 45X (emergency department) or 516 (urgent care center) revenue code, then OCE logic should determine that this was a direct admission to observation care. If the hospital bills the GXXXX code with a 45X or 516 revenue code, then it is clear that the patient came in through ED or

urgent care center. Once such logic is programmed into the OCE, it would be up to the system to determine whether the observation is a result of a direct admission or not and pay accordingly.

Oakwood Healthcare, Inc. seeks clarification regarding the reference to inpatient status in the statement on page 42743 in the proposed rule that states "That is, hospitals would bill GXXXX when observation services are provided to any patient admitted to 'observation status,' regardless of the patient's status as an *inpatient* [emphasis added] or outpatient." We are concerned about this statement because if a patient is admitted as an inpatient, the hospital would not report HCPCS codes, but instead would be using the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) codes since ICD-9-CM is the Health Insurance Portability and Accountability Act code set standard for reporting procedures for hospital inpatient reporting.

PAYMENT FOR INTERRUPTED PROCEDURES
(Federal Register pages 42751 – 42753)

The CMS proposes to decrease payment from 100 percent to 50 percent for interrupted procedures coded with modifiers 52 (discontinued procedure, no anesthesia provided) or 74 (procedure discontinued after administration of anesthesia). However, no analysis was conducted to support the reduction.

These modifiers cannot be used for elective cancellations; therefore, the procedures generally have been interrupted due to clinical reasons. In the event that a procedure is interrupted because a patient is having medical problems, costs may actually increase, not decrease, as the team addresses the patient's needs. Detailed claims analysis is needed to determine whether these additional costs could be covered through additional billed services or not. In any event, much of the hospital's costs have already been incurred at this point. For example, the operating room will have been occupied during the start of the procedure and must still be prepared for the next patient. Similarly, sterile supplies will have been opened and will either be disposed of or be reprocessed at additional cost.

Oakwood Healthcare, Inc. believes that before the CMS establishes reductions in payments for procedures billed using these modifiers, there must be evidence supporting the need for payment reductions and the level of reductions that would be applied.

PHYSICIAN OVERSIGHT OF NON-PHYSICIAN PRACTITIONERS
(Federal Register pages 42753 – 42754)

Oakwood Healthcare, Inc. supports the CMS's proposal to defer to State law regarding the need for physicians to review and sign the medical records for outpatients cared for by non-physician practitioners in critical access hospitals (CAHs). However, we also recommend that the CMS extend the application of this policy to physician review of inpatient records for patients cared for by non-physician practitioners. If state law permits these practitioners to practice independently, the CMS should not require physician oversight in either the outpatient or inpatient setting. We agree that State laws providing independent

practice authority generate sufficient control and oversight of these non-physician practitioners and we do not believe that quality of care is reduced by non-physician practitioners.

Oakwood Healthcare, Inc. also supports the additional flexibility the CMS adds under this proposed policy for those states that do not allow for independent practice of non-physician practitioners – in particular permitting the facility to establish policy regarding the sample size of outpatient records to be reviewed and signed, consistent with current standards of practice.

Thank you for your review and consideration of these comments. If you have any questions, please contact me at 313-586-5717 or via email at michele.desmet@oakwood.org.

Sincerely,

Michele DeSmet
Reimbursement Manager
Oakwood Healthcare, Inc.

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Submitter : Michele DeSmet **Date:** 09/14/2005

Organization : Oakwood Healthcare, Inc.

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-416-Attach-1.DOC

September 14, 2005

Centers for Medicare and Medicaid Services
Department for Health and Human Services
Attn: CMS 1500-P
PO Box 8011
Baltimore, MD 21244-1850

Re: **CMS-1501-P**
Medicare Program; Changes to the Outpatient Prospective Payment System and 2006 Rates; Proposed Rule, July 25, 2005 *Federal Register*

Dear Dr. McClellan:

Oakwood Healthcare, Inc. welcomes this opportunity to comment on the proposed rule promulgated by the Centers for Medicare and Medicaid Services ("CMS") regarding the Medicare Outpatient Prospective Payment System for calendar year 2006, as published in the July 25, 2005 *Federal Register*. Oakwood Healthcare, Inc., located in Dearborn, Michigan, operates four not-for profit acute care hospitals with 1,307 licensed beds.

HOSPITAL MARKET BASKET INCREASE

(*Federal Register Page 42694-42695)*

The hospital update is based on a "marketbasket" factor that is intended to reflect the average change in the price of goods and services hospitals purchase to furnish patient care. These price changes must be projected forward to estimate increases for the subsequent year so that an appropriate marketbasket update can be determined in advance of payment. The payment system is prospective, and the update is not retroactively reconciled to reflect actual price increases for the year. Therefore, a reliable projection methodology is vital to ensure equitable payments.

For the hospital inpatient PPS, the FY 2006 inpatient proposed rule included a 3.2 percent update, with the actual increase in the final rule set at 3.7 percent, based upon a change in methodology. **Oakwood Healthcare, Inc. requests that the CMS revise the marketbasket update included in the final OPPS rule to include a 3.7 percent marketbasket update, consistent with the inpatient final rule.**

COST OUTLIER PAYMENT THRESHOLDS

(*Federal Register* pages 42701- 42702)

The CMS provides outlier payments for individual services or procedures with extraordinarily high costs compared to the payment rates of the APC group. For the 2005 OPPS, outlier payments are made for services with costs that exceed 1.75 times the APC payment rate and the APC rate plus a $1,175 fixed-dollar threshold. This dual test was intended to eliminate outlier payments for low-cost services and provide higher outlier payments for more expensive procedures.

Since implementation of the OPPS in August 2000, the CMS has set aside a targeted outlier payment pool of 2.0 percent of total OPPS payments. In the proposed rule, the CMS cited the Medicare Payment Advisory Commission's (MedPAC) March 2004 report, which suggests Congress should eliminate the outlier policy under the OPPS. The CMS states that, although elimination of outlier payments would require a statutory change, many of the reasons cited by MedPAC justify a reduction in the size of the outlier payment pool.

For 2006, the CMS is proposing to set a projected target for aggregate outlier payments at 1.0 percent of aggregate total payments under the OPPS. In order to ensure that estimated 2006 aggregate outlier payments would equal 1.0 percent of estimated aggregate total payments under OPPS, the CMS is proposing that the outlier threshold be modified so that outlier payments are made when the cost of furnishing a service or procedure by a hospital exceeds 1.75 times the APC payment amount and exceeds the APC payment rate plus a $1,575 fixed dollar threshold, which is $400 more than the current threshold. The CMS will continue to pay 50 percent of the amount by which the cost of furnishing the service exceeds 1.75 times the APC payment rate when the cost of a hospital outpatient service exceeds these thresholds. The proposed change to reduce the outlier pool by 1 percent will be implemented in a budget-neutral manner by increasing the APC conversion factor by 1 percent.

Oakwood Healthcare, Inc. is concerned about the re-distributional impact of this change, which we believe is inappropriate. In the inpatient final rule, the CMS indicated its charge estimate was too high, and lowered the threshold considerably in the final rule. If the CMS is using the same charge estimates for purposes of the OPPS proposed rule, then the agency should make a similar adjustment to the methodology used to calculate the threshold in the OPPS final rule. In addition, for the past four years, the CMS set aside two percent of total estimated OPPS payments to fund hospital outlier payments. For 2006, the CMS is proposing to set aside only one percent for outlier payments. However, the agency does not publicly release data regarding how much of the established outlier pool was actually spent in prior years in the *Federal Register* or on its website. Due to the significant changes to outlier policies proposed for 2006, Oakwood Healthcare, Inc. is concerned that Medicare may not actually spend the entire one percent pool. Therefore, **we strongly recommend that in the final rule, the CMS publish data regarding actual outlier payments made in 2004 and prior years, and to report this data in the future.** We also seek further clarification from the CMS regarding how the $1,575 fixed dollar threshold was calculated. In addition, we **urge the CMS to maintain the outlier threshold at the current level and to maintain the total outlier pool at the current 2.0 of aggregate OPPS payments.**

MULTIPLE DIAGNOSTIC IMAGING PROCEDURES

(Federal Register pages 42748 - 42751)

Currently, hospitals receive a full APC payment for each diagnostic imaging procedure on a claim, regardless of how many procedures are performed using a single imaging modality and whether or not contiguous areas of the body are studied during the same encounter.

In its March 2005 Report to Congress, MedPAC recommended improved Medicare coding edits that would detect unbundled diagnostic imaging services and reduce the technical component payment for multiple imaging services when they are performed on contiguous areas of the body. Currently, payment rates are based on each service being provided independently and the rates do not account for efficiencies that may be gained when multiple studies using the same imaging modality are performed in the same session. For surgical procedures, the OPPS has a longstanding policy of reducing payment for multiple procedures performed on the same patient during the same operative session. In such cases, full payment is made for the procedure with the highest APC payment rate, and each subsequent procedure is paid at 50 percent of its respective APC payment rate.

For 2006, the CMS is proposing to pay 100 percent for the diagnostic imaging procedure with the highest APC payment rate, and pay only 50-percent for each additional imaging procedure when all the procedures are performed during a single patient encounter and all are within an identified "family" of procedures that are commonly billed on the same day. The CMS identified 11 "families" of imaging procedures by imaging modality and by contiguous body area. The agency is proposing to apply the multiple imaging procedure reduction to individual services described by codes within one Family, not across Families. For example, no reduction would apply to an MRI of the brain (CPT code 70552) in code Family 5, when performed in the same session as an MRI of the spinal canal and contents (CPT code 72142) in code Family 6. The CMS is proposing to make full payment for the procedure with the highest APC payment rate, and payment at 50 percent of the applicable APC payment rate for each additional procedure, when performed in the same session. In developing this policy, the CMS did not examine hospital cost data but relied on Medicare physician fee schedule practice expense data for determining the discount level. No evidence has been presented to justify the reduction in payment or to suggest that the 50 percent discount represents the appropriate level of efficiencies obtained by hospitals, if they even exist.

Oakwood Healthcare, Inc. opposes moving forward with this policy without solid justification, and more substantial, hospital-based data to support the policy. We note that the APC Advisory panel came to the same conclusion. Additional concerns include:

- how this policy would be applied; use of the Medicare physician fee schedule practice expense data for determining the level of the discount;
- the policy lacks detail and justification for the 50 percent discount;
- how the CMS would define the "same session". In some circumstances a patient may have a procedure performed earlier in the day and subsequently on the same day have another procedure that may fall within the same family and incorrectly be subject to the discount.

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PHARMACY OVERHEAD & DRUG HANDLING – PAYMENT RATE ADJUSTMENT
(Federal Register pages 42728 – 42731)

The MMA required MedPAC to submit a report to the HHS Secretary on adjusting the APC rates for specified covered outpatient drugs, taking into account overhead and related expenses, such as pharmacy services and handling costs. The provision required a recommendation as to whether payment adjustment should be made; and the methodology for adjusting payment, if an adjustment is recommended. MedPAC concluded that the handling costs for drugs, biologicals, and radiopharmaceuticals delivered in the hospital outpatient setting are significant, as medications administered in outpatient departments generally require greater pharmacy preparation time that those provided in the inpatient setting.

For 2006, the CMS did not propose to create separate handling categories for radiopharmaceutical agents. However, for drugs and biologicals, the CMS proposes to establish three distinct HCPCS C-codes and corresponding APCs for drug handling categories to differentiate overhead costs for drugs and biologicals and instruct hospitals to charge the appropriate pharmacy overhead C-code for overhead costs associated with administration of each separately payable drug and biological based on the code description that best reflects the service required by the hospital in preparing the pharmaceutical product for administering to a patient. Since the CMS does not have separate hospital charge data for pharmacy overhead, for 2006, they propose to pay for these costs based on two percent of the Average Sales Price (ASP). This would result in overall drug payments, including the drug itself and the associated handling payment, of ASP + 8 percent which is a rate that the CMS states is equivalent, on average, to the mean cost for drugs derived from hospital claims data.

Oakwood Healthcare, Inc. agrees with the MedPAC finding that handling costs for drugs and biologicals delivered in the hospital outpatient department are significant and should be reimbursed by Medicare. We believe that, while imperfect, the ASP + 2 percent adjustment for drug handling would be appropriate as a temporary measure. In the future, the CMS should work with hospital and pharmacy stakeholders to develop an approach to establish differential add-on payments for drug handling costs to account for a wide variety of drug handling categories.

Oakwood Healthcare, Inc. is strongly opposed to the CMS' proposal to require hospitals to establish separate charges for pharmacy overhead for separately payable drugs and biologicals and to utilize the three proposed C-codes for charging these overhead costs. This would be extremely burdensome for hospitals to implement. There are many complex issues and administratively burdensome aspects to adopting the CMS proposal for charging drug handling through the use of these new C-codes. These issues include:

- Hospitals will have to evaluate the normal mark-up formula for all pharmacy items and pull out the handling costs for some, but not all, of these drugs and biologicals. That is, hospitals would have to identify and strip out the handling charges for

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- Many hospitals use the same charge master for inpatient and outpatient services. If the handling charge must be separated out of the drug charge for the outpatient setting, there are questions regarding how the CMS will expect providers to report drug charges in the inpatient setting versus the outpatient setting.

Oakwood Healthcare, Inc. strongly opposes this expansion of the drug handling C-coding proposal to packaged drugs. This would exponentially increase the coding and administrative burden on hospitals due to the sheer number of drugs that would require special charging practices for Medicare purposes. In addition, we strongly recommend that the CMS does not implement the proposed drug handling C-codes in 2006, but we suggest that the CMS work with stakeholder groups to collect further data and develop alternative and simplified solutions for ensuring that hospitals are appropriately paid for their pharmacy overhead and drug handling costs and the CMS obtains the information that it desires. If the CMS decides to proceed with implementing this burdensome drug-handling C-does policy, then Oakwood Healthcare, Inc. strongly suggests that the CMS provide a grace period of no less than 90 days after implementation of the 2006 OPPS, or until April 1, 2006, to allow hospitals to make necessary system changes, educate pharmacy staff, finance staff and coders on the required use of the drug handling "C" codes.

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(Federal Register pages 42745 – 42746)

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(Federal Register pages 42680 – 42692)

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BLOOD & BLOOD PRODUCTS
(Federal Register pages 42740 – 42742)

The CMS proposes to continue making separate payments for blood and blood products through individual APCs for each product. The agency also proposes to establish payment rates for blood and blood products based on their 2004 claims data, utilizing an actual or simulated hospital blood-specific cost-to-charge ratio to convert charges to costs for blood and blood products. For blood and blood products whose 2006 simulated medians would experience a

decrease of more than 10 percent in comparison to their 2005 payment medians, the CMS is proposing to limit the decrease in medians to 10 percent.

While this approach results in modest payment increases for many blood and blood product APCs, the payment rate for leukocyte-reduced red blood cells (APC 0954), the most commonly transfused blood product, and rates for certain other blood and blood product APCs will continue to decline under this methodology. According to data from the American Association of Blood Banks, the proposed rate for several of these blood products is significantly below hospitals' actual acquisition cost for blood, most notably for leukocyte-reduced red blood cells, and, with the introduction of additional blood safety measures, it is likely that the cost of these products will continue to increase, making the proposed Medicare payment rate even more inadequate.

To ensure continued beneficiary access to all blood and blood products, Oakwood Healthcare, Inc. recommends that CMS set 2006 rates at *the greater of*: (1) the simulated medians calculated using the 2004 claims data; or (2) the 2005 APC payment medians for these products.

OBSERVATION SERVICES
(Federal Register pages 42742 – 42745)

Currently, Medicare provides a separate observation care payment for patients with congestive heart failure (CHF), chest pain, and asthma. In order to reduce administrative burden on hospitals when attempting to differentiate between packaged and separately payable observation services, the CMS proposes to discontinue current HCPCS codes for observation services (G0244, G0263, and G0264) and instead create two new HCPCS codes to be used by hospitals to report all observation services: GXXXX (Hospital observation services, per hour) and GYYYY (Direct admission of patient for hospital observation care). The CMS would shift determination of whether or not observation services are separately payable under APC 0339 from the hospital billing department to the outpatient PPS claims processing logic contained in the Outpatient Code Editor (OCE) system.

Oakwood Healthcare, Inc. supports the concept of allowing the OCE logic to determine whether services are separately payable as this will result in a simpler and less burdensome process for ensuring payment for the provision of covered outpatient observation services. The existing G codes for observation services, with their long, complex descriptors that encompassed all variables required for claim processing into a single code, create a significant administrative burden for hospital coders and billers. We are pleased that CMS has found a method to reduce the burden by simplifying the G codes required for observation services and making changes to the OCE logic.

However, we believe that the OCE logic could be used even more efficiently by making the HCPCS code GYYYY (Direct admission of patient for hospital observation care) unnecessary. If the hospital bills the GXXXX code and the claim *does not* include a 45X (emergency department) or 516 (urgent care center) revenue code, then OCE logic should determine that this was a direct admission to observation care. If the hospital bills the GXXXX code with a 45X or 516 revenue code, then it is clear that the patient came in through ED or

urgent care center. Once such logic is programmed into the OCE, it would be up to the system to determine whether the observation is a result of a direct admission or not and pay accordingly.

Oakwood Healthcare, Inc. seeks clarification regarding the reference to inpatient status in the statement on page 42743 in the proposed rule that states "That is, hospitals would bill GXXXX when observation services are provided to any patient admitted to 'observation status,' regardless of the patient's status as an *inpatient* [emphasis added] or outpatient." We are concerned about this statement because if a patient is admitted as an inpatient, the hospital would not report HCPCS codes, but instead would be using the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) codes since ICD-9-CM is the Health Insurance Portability and Accountability Act code set standard for reporting procedures for hospital inpatient reporting.

PAYMENT FOR INTERRUPTED PROCEDURES
(Federal Register pages 42751 – 42753)

The CMS proposes to decrease payment from 100 percent to 50 percent for interrupted procedures coded with modifiers 52 (discontinued procedure, no anesthesia provided) or 74 (procedure discontinued after administration of anesthesia). However, no analysis was conducted to support the reduction.

These modifiers cannot be used for elective cancellations; therefore, the procedures generally have been interrupted due to clinical reasons. In the event that a procedure is interrupted because a patient is having medical problems, costs may actually increase, not decrease, as the team addresses the patient's needs. Detailed claims analysis is needed to determine whether these additional costs could be covered through additional billed services or not. In any event, much of the hospital's costs have already been incurred at this point. For example, the operating room will have been occupied during the start of the procedure and must still be prepared for the next patient. Similarly, sterile supplies will have been opened and will either be disposed of or be reprocessed at additional cost.

Oakwood Healthcare, Inc. believes that before the CMS establishes reductions in payments for procedures billed using these modifiers, there must be evidence supporting the need for payment reductions and the level of reductions that would be applied.

PHYSICIAN OVERSIGHT OF NON-PHYSICIAN PRACTITIONERS
(Federal Register pages 42753 – 42754)

Oakwood Healthcare, Inc. supports the CMS's proposal to defer to State law regarding the need for physicians to review and sign the medical records for outpatients cared for by non-physician practitioners in critical access hospitals (CAHs). However, we also recommend that the CMS extend the application of this policy to physician review of inpatient records for patients cared for by non-physician practitioners. If state law permits these practitioners to practice independently, the CMS should not require physician oversight in either the outpatient or inpatient setting. We agree that State laws providing independent

practice authority generate sufficient control and oversight of these non-physician practitioners and we do not believe that quality of care is reduced by non-physician practitioners.

Oakwood Healthcare, Inc. also supports the additional flexibility the CMS adds under this proposed policy for those states that do not allow for independent practice of non-physician practitioners – in particular permitting the facility to establish policy regarding the sample size of outpatient records to be reviewed and signed, consistent with current standards of practice.

Thank you for your review and consideration of these comments. If you have any questions, please contact me at 313-586-5717 or via email at michele.desmet@oakwood.org.

Sincerely,

Michele DeSmet
Reimbursement Manager
Oakwood Healthcare, Inc.

F:\Medicare\FY2006\Comment on OP FY06 9-05.doc

Submitter : **Ms. Laurel Patt** **Date: 09/14/2005**

Organization : **Middlesex Hospital**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

attachment

CMS-1501-P-417-Attach-1.DOC

MIDDLESEX
HOSPITAL

The Honorable Mark McClellan
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
Room 445-G
200 Independence Avenue, S.W.
Washington, D.C. 20201

ATTN: FILE CODE CMS-1501-P
Re: Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates

Dear Dr. McClellan:

I am writing on behalf of the Middlesex Hospital on an issue of great importance to Medicare beneficiaries with cancer. Middlesex Hospital's cancer center and cancer research benefits a large geographic region with in Connecticut. Positron Emission Tomography (PET) procedures are an integral part of the Middlesex Hospital program to diagnose and manage patients with cancer. We are pleased that the Centers for Medicare and Medicaid Services (CMS) has recently proposed to expand cancer coverage for PET scans. However, we are concerned, that the proposed hospital outpatient payment rate for PET/CT scans is inadequate to cover hospital costs for this new technology.

The PET/CT scanner is the latest advance in oncology imaging which combines two state-of-the-art imaging modalities. PET alone provides physicians with information about the body's chemistry, cell function, and metabolism that anatomic imaging modalities such as CT and MRI are unable to provide, but does not provide the exact anatomic location of the signal in the body. CT provides anatomic information regarding the location, size, and shape of various lesions, however it cannot differentiate cancerous lesions from normal structures with the same accuracy as PET. The combined PET/CT scanner merges PET and CT images together, thereby more accurately identifying and localizing tumors in the body.

Middlesex Hospital has decided to offer our patients the best technology for managing cancer as represented in the combined PET/CT technology. We are very concerned about the proposed payment rate for PET/CT. The proposed payment rate of $1250 is well below our cost for these scans. Without adequate reimbursement, beneficiary access to PET/CT will be limited.

Therefore, I strongly urge you to consider an increased payment rate for PET/CT to represent true costs for hospitals.

Thank you very much for your attention. Please feel free to contact me with more information.

Very truly yours,

Laurel A. Patt, Radiology Director

28 Crescent Street
Middletown, Connecticut 06457-3650

tel 860 344-6000
www.middlesexhealth.org

28 Crescent Street
Middletown, Connecticut 06457-3650

tel 860 344-6000
www.middlesexhealth.org

A member of the Middlesex Health System

Submitter : Mr. David Harris

Date: 09/14/2005

Organization : Medical Management Options, Inc.

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-418-Attach-1.DOC

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

September 12, 2005

Re: Comment to CMS-1501-P Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates – Proposed Rule

Medical Management Options, Inc. operates Community Mental Health Centers in three Parishes (Baton Rouge, Ascension, and Lafayette) in Louisiana. This year we will provide over 24,000 patient days of care to over 700 seriously mentally ill residents of Louisiana in our partial hospitalization programs alone. In addition, the three partial hospitalization programs provide employment to 58 Louisiana residents with an annual payroll exceeding $1,500,000.

We are writing to object to the CMS proposed 15% rate reduction for partial hospitalization programs for Calendar Year 2006. For the first half of 2005 our cost for providing this service averaged $231.64 per day. The proposed wage-adjusted rate for our area is $220.38 resulting in a net loss of $11.26 per patient per day of service provided. The interim rate proposed is $176.30 resulting in a cash flow deficit of $55.34 per patient per day. Based on statistics for this year we will lose over $262,000 per year and experience an annual cash flow deficit of almost $1,300,000. These losses will only be magnified by the large influx of patients into our area due to hurricane Katrina.

We believe that, instead of implementing this drastic cut, CMS should increase the per diem rate paid to Community Mental Health Centers providing partial hospitalization services to at least the rate paid to hospital outpatient mental health departments that treat a population with a significantly lower acuity. The average proposed rate per unit of service for hospital outpatient mental health services is $77.93. This would equal $311.72 for the four units of service required as a minimum service level for partial hospital programs.

Thank you for considering these comments.

Sincerely,

David Harris

Submitter : **Dr. Helen Waters** **Date: 09/14/2005**

Organization : **CNY Ear, Nose and Throat Consultants**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

Submitter : Mr. Daniel Smith **Date:** 09/14/2005

Organization : American Cancer Society

Category : Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-420-Attach-1.TXT

September 14, 2005

Mark McClellan, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

RE: CMS-1501-P; Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; Proposed Rule

Dear Dr. McClellan:

On behalf of the American Cancer Society ("the Society") and its millions of volunteers and supporters, we respectfully submit the following comments for your consideration regarding the Centers for Medicare & Medicaid Services' (CMS') proposed changes to the Hospital Outpatient Prospective Payment System (OPPS) and calendar year (CY) 2006 payment rates, CMS-1501-P, as published in the Federal Register on July 25, 2005.

As the nationwide voluntary health organization committed to eliminating cancer as a major health problem, the American Cancer Society has a particular interest in ensuring that our nation's seniors have access to high quality cancer prevention, early detection, and treatment tools through the Medicare program. As you may know, cancer is a disease that disproportionately affects the elderly—according to the Society's 2005 Facts & Figures, nearly 76% percent of all new cancer diagnoses occur in this population. Given the importance of hospital outpatient services to cancer patients, the Society appreciates the opportunity to provide you with comments on the hospital OPPS.

Proposed Hospital OPPS Changes

Payment for Multiple Imaging Services

Hospitals billing for diagnostic imaging procedures currently receive full APC payment for each billed service, regardless of how many procedures are performed using a single imaging modality and whether or not contiguous areas of the body are studied in the same session. In a March 2005 report to Congress, MedPAC recommended that the Secretary improve Medicare coding edits that detect unbundled diagnostic imaging services and reduce the technical component payment for multiple imaging services when they are performed on contiguous areas of the body. MedPAC noted that Medicare's payment rates are based on each service being provided independently and that the rates do not account for efficiencies that may be gained when multiple studies using the same imaging modality are performed in the same session. According to MedPAC's report, hospitals may experience savings in clerical time, technical preparation and medical supplies when multiple studies of the same modality are performed on

contiguous body parts during a single patient encounter.

In response to MedPAC's recommendations, CMS has proposed to make a 50% reduction in hospital OPPS payments for some second and subsequent imaging procedures performed during the same session, thereby adopting a policy that is followed by some private insurers. Reductions would apply when more than one procedure within contiguous areas of the body is performed in the same session. The Society is concerned that some hospitals may choose to no longer provide certain imaging services due to reduced reimbursement rates. Cancer patients frequently use imaging procedures both in terms of staging their disease but also to monitor the efficacy of cancer treatment. Cutting reimbursement for imaging procedures performed in the same session might create a barrier to access for cancer patients if reimbursement rates are too low. The Society plans to monitor the impact of this provision on cancer patients' access to care.

Special packaging rule for certain anti-emetics

The Society is pleased that CMS has proposed to continue the policy it adopted for 2005 of exempting the oral and injectible 5HT3 anti-emetic products from the packaging rule, thereby making separate payment for all of the 5HT3 anti-emetic products.

As CMS is aware, chemotherapy is difficult for many patients to tolerate because the side effects are often debilitating. Anti-emetic use is often an integral part of the treatment regimen, allowing cancer patients to achieve the maximum therapeutic benefit from chemotherapy while helping to control side effects such as nausea and vomiting. Separate payment for anti-emetic products helps ensure that these vital therapies are available for the beneficiaries who need them.

Conclusion

The proposed hospital OPPS rule has the potential to affect millions of Medicare beneficiaries diagnosed and living with cancer. We appreciate CMS' efforts in implementing the many provisions in this proposed rule and we stand ready to work with you and your staff to meet our mutual goals of improving the health and reducing the cancer burden among Medicare beneficiaries.

Respectfully,

Daniel E. Smith
National Vice President
Federal and State Government Relations
National Government Relations Office

Wendy K. D. Selig
Vice President
Legislative Affairs

901 E Street, NW, Suite 500 Washington, DC 20004

Submitter : Dr. Steven Telian

Date: 09/14/2005

Organization : University of Michigan

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-421-Attach-1.DOC

September 13, 2005

Centers for Medicare and Medicaid Services
US Department of Health and Human Services
Attention: CMS-1501-P

Re: File Code: CMS-1501-P
Issue Identifier: Device-dependent APCs

To Whom It May Concern:

I am writing as the medical director of the cochlear implant program at the University of Michigan. Our institution has provided over 1000 cochlear implants to profoundly hearing impaired individuals since the mid 1980's. I am writing to oppose the proposed reduction in payment for cochlear implantation in 2006.

Cochlear implantation has always been a procedure where medical institutions and cochlear implant programs have been unable to reclaim the full cost of providing services. However, the medical community has been so strongly motivated to provide this benefit to deaf individuals that most programs have been allowed to continue functioning. The long-term viability of this approach to cochlear implant services is tenuous at best. Further reduction in reimbursements will have a negative impact on the ability of cochlear implant programs to remain open.

I am sure you are aware of the extraordinary benefits that cochlear implantation can provide to deaf individuals. The cost effectiveness of cochlear implantation is well documented in the medical literature. Several evidence based studies document that this technology is more cost effective than coronary artery bypass grafting and other well accepted medical procedures. In addition, the cost savings to society in reduction of educational costs and long-term welfare benefits are immense.

If the proposed cost reductions are implemented, it is possible that there could be a severe impact on the access of Medicare beneficiaries to cochlear implantation. I would strongly encourage the Centers for Medicare and Medicaid Services to reconsider this proposed reduction and rather seek to gradually improve coverage for this important medical device in future years.

Sincerely yours,

Steven A. Telian, M.D.
John L. Kemink Professor and
Director, Division of Otology/Neurotology

SAT:bc

Submitter : Mr. JOHN MANTER **Date:** 09/14/2005

Organization : Mr. JOHN MANTER

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Observation Services

I am writing to request reconsideration, or better explanation ,for the OCE Observation logic that rejects observation claims that have a status T procedure on the claims.

Quite often, chest pain observation patients undergo cardiac cath evaluations, which is a status T procedure. The current rule seems to undercut payment in this situation, or in the case of cardiac cath patients who develop complications during or after the procedure.

Alternately, the distinction between status S and status T procedures as a means test for observation rejection seems artificial. Status T designation was introduced for multiple procedure discounting, and intensity and type of service for S and T procedures can be similar. For example, fracture reduction codes are status T, but fracture splinting codes are status S. The surgical codes for vascular angioplastics are status T, but the radiological component is status S.

With the hope and expectation that other conditions besides chest pain, asthma, and COPD will eventually qualify for observation payment, the status T rule raises other questions. Breast procedures and many Interventional Radiology procedures have status T designation. Procedural complications or physician planned overnight observation can apply to these status T procedures.

I suggest that for consistency that status S procedures be included with status T for claims editing, or that this edit be suspended. Thank you for this opportunity to respond to the proposed OPPS rule.

Submitter : Ms. Renee Tyminski **Date:** 09/14/2005

Organization : FHS Wound Care Center

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

Proposed rule CMS-1501-P contains some errors which would seriously undermine wound care in the United States. Although the proposed rule is intended to provide improved reimbursement the reimbursement rate for Apligraf is approximately $400.00 less then what the product cost to purchase in an outpatient setting and Dermagraf reimbusement is approximately $200.00 less then the purchase price. Reimbursement at this rate would jeopardize patient access to Apligraf and dermagraf and that would have a very negative impact on quality of care for patients. Apligraf is an advanced treatment used for treatment of patients with venous leg ulcers and diabetic foot ulcers, some who have had these wounds for years. Apligraf and Dermagraf are important elements of wound care which lead to faster healing rates, decreased infections andsubsequently less amputations.

Submitter : **Dr. Richard Herlihy** **Date: 09/14/2005**

Organization : **The Urology Group**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-425-Attach-1.DOC

September 9, 2005

Mark B. McClellan, M.D. Ph.D
Administrator
Center for Medicare/Medicaid Services
Department of Health and Human Services
Attention: CMS-150-P
P.O. Box 8016
Baltimore, Maryland 21244-8018

Re: AMS-1501-P Medicare Programs
Changes to the Hospital Outpatient Perspective Payment System &
Calendar Year 2006
Payment Rates for APC 674:Cryosurgery of the Prostate

Dear Dr. McClellan:

Medicare has proposed a decrease in the reimbursement rate for APC 674, cryosurgery of the prostate. I am concerned that decreasing payment for this new technology will prevent hospitals being able to offer that new technology to patients. I feel that cryosurgery has an important part in the treatment of prostate cancer. It treats a segment of patients that are not good candidates for other forms of therapy. I think you should reconsider your decrease in reimbursement.

Sincerely,

Richard E. Herlihy, M.D.

REH/emd

Submitter : Standish Fleming

Date: 09/14/2005

Organization : Forward Ventures

Category : Private Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-426-Attach-1.DOC

FORWARD VENTURES

9393 Towne Centre Drive, Suite 200
San Diego, CA 92121

September 14, 2005

The Honorable Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
P.O. Box 8016
Baltimore, MD 21244-8018

Re: Proposed Changes to the OPPS Payment System and 2006 Payment Rates

Issue: New Technology APC

Dear Dr. McClellan:

Forward Ventures is pleased to submit these comments to the Centers for Medicare and Medicaid Services (CMS) in response to the July 25, 2005 *Federal Register* notice regarding the 2006 Hospital Outpatient Prospective Payment System (HOPPS) proposed rule.

We would like to thank CMS for the opportunity to make recommendations regarding the proposal to require the submission of a CPT code application as part of the New Technology APC criteria.

New Technology APCs

CMS proposes to require that an application for a code for a new technology service be submitted to the American Medical Association's (AMA) CPT Editorial Panel before CMS will accept a New Technology APC application for review. Furthermore, CMS is proposing that a copy of the submitted CPT application be submitted to CMS as a part of the application for a New Technology APC. CMS is also proposing to require a letter from the AMA acknowledging the CPT code application.

Forward Ventures is concerned that the AMA CPT Editorial Panel may not be an appropriate forum for a federally mandated new technology decision. This requirement may add unnecessary delay of new technology to Medicare beneficiaries preventing rapid availability of new technology as intended by the MMA legislation.

The AMA CPT Editorial Panel is a private organization, utilizing closed processes, that are not subject to procedural protections typically required for public policy. AMA meetings are closed to the public and the bases for decisions are not available to the public, including hospitals and physicians. The AMA CPT Editorial Panel allows no participation or representation from the medical technology industry and manufacturer community. Further, the panel is not subject to the protections of the Administrative Procedures Act, the Freedom of Information Act, or the Federal Advisory Committee Act.

Clearly, the requirement of the submission to the AMA CPT Editorial Panel would require involvement of an organization that may not be accountable as are all other agencies that are subject to federal public policy decisions.

The requirement to submit New Technology APC applications together with CPT code applications presents an inherent conflict of purpose. By definition, category I CPT codes are assigned to procedures that have become an accepted standard of care and are in widespread use. This conflicts with and, in fact, defeats the purpose of creating a special coding vehicle (new technology APCs) to facilitate adoption and dissemination of new technology and the collection of clinical data. If manufacturers are forced to apply for a CPT code before widespread use or extensive information about the technology is available, it is likely that the CPT Editorial Panel would assign a Category III (emerging technology) code. This often results in a non-coverage decision by local Medicare carriers and fiscal intermediaries and many commercial payers thus denying Medicare patients access to technology. The end result of the proposed rule would be a disincentive for manufacturers, particularly smaller ones, to innovate and market novel and beneficial medical technologies.

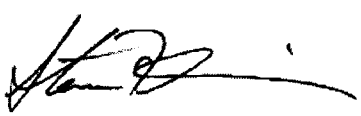
If the AMA CPT Editorial Panel were to agree to open its meetings to the public, place voting representatives from manufacturers on the decision making panel and offer additional concerned parties the opportunity to participate, comment, and otherwise comply with the Administrative Procedures Act, Freedom of Information Act, and Federal Advisory Committee Act, then the proposed role of the AMA would more likely support continued rapid access of new technologies to Medicare patients. Until this time we recommend that CMS eliminate the proposed requirement that manufacturers submit a CPT application prior to submission of a New Technology APC application to CMS.

New technology continues to offer important treatment for Medicare patients. Appropriate and timely payment for new technologies permit Medicare beneficiaries full access to the same high quality care in the hospital outpatient setting realized by patients covered by private insurance.

We hope that CMS will take these issues under consideration during the development of the HOPPS Final Rule and eliminate the proposed requirement for a CPT application submission prior to the New Technology APC application.

Should CMS staff have additional questions, please contact me.

Sincerely yours,



Standish M. Fleming
Managing Member
Forward Ventures
Phone: 858-964-5001
9393 Towne Centre Drive, Suite 200
San Diego, CA 92121

Submitter : Mrs. Catherine Meeter **Date:** 09/14/2005

Organization : Sutter health

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Sutter Health would like to submit a comment re: CPT code 97602 found on page pages 42691 and 42692 of the proposed rules for OPPS for 2006, Section II - Proposed Updates Affecting Payments for CY 2006, #4 - Proposed Changes to Packaged Services #10. CMS indicated that they referred this CPT code for MPFS evaluation of its bundled status. It is assigned to a SI of A for the 2006 proposed rules and CMS stated that the payment policy for this bundled service has not changed and separate payment will not be made. I wish to ask CMS to reconsider their stance on this and ask that the code not be considered bundled and to make separate payment when the code is submitted. We have physicians who do send patients to our hospitals to provide this service. Part of the problem is that this code has been designated by CMS as a therapy only code when in fact we have qualified wound therapy nurses who provide this service. It seems logical that if a patient comes in for this service, and it is provided by a wound care nurse, the hospital should be allowed to report this code without a therapy modifier and the hospital should be paid. Otherwise, the only other option is for the hospital to report an E & M code which really does not give CMS accurate data as to what was performed. In summary, we are asking CMS two things: to remove this code from the therapy only list, i.e. to allow use of this code when service is provided by a wound care nurse (or person other than a therapist)and that payment be made to the hospital if this is submitted as the single service provided.

Submitter : Ms. Siobhan Mee Mee **Date:** 09/14/2005

Organization : Maricopa Integrated Health System

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attached

CMS-1501-P-428-Attach-1.DOC

Department of Revenue Management
Maricopa Integrated Health System

Maricopa Integrated Health System
Business Office
2619 E. Pierce Street,
1st Floor
Phoenix, AZ 85008

Centers for Medicare & Medicaid Services
Department of Health and Human Services, Attention CMS 1501-P
P.O. Box 8016 Baltimore MD 21244-8018

I have reviewed the proposed OPPS changes for 2006 and discussed with the affected departments. Listed below you will find our comments and concerns for your consideration:

- Proposed C-Codes to capture drug handling
  - Do the proposed codes have a specific revenue code to be used?
  - Is there a one to one relationship between the drug and the handling code? If so there are not enough handling codes to correspond to the drug codes.
  - Our current host systems do not have a method to tie more than one HCPC/Revenue Code to any drug. Data capture would require the manual entry of an additional pseudo charge.
  - Is the drug payment tied to the handling C-Code.
  - For compounded drugs are more than one handing codes to be used or is coding based on the primary ingredient.
  - Will private payors to be required to recognize these codes and not reject claims or are the providers expected to bill private payors differently than CMS?
- Proposed changes to Payment for Modifier 74

  Currently several of our endoscopic procedures require anesthesia based on the ASA requirements. Once anesthesia has been administered and the procedure started we have committed our full set of resources and subsequent expenses to the case. Two current endoscopy procedures (PEG placement and ERCP) always require anesthesia and a significant amount of recovery time. Unless Narcan could be administered safely post anesthesia administration we would not foresee any reduction in expense.
- Changes to Drug Administration definitions.
  - Changes to the description will require more codes, extensive education and documentation although the payments will still remain at a per visit APC.
  - Proposed definition changes need clarification. Are we to use the physician office definition? Using the physician definitions for these changes creates a tracking and documentation issue as many patients have administration in multiple hospital departments which makes the use of initial unclear. Initial for that department or initial for the entire health system.

Siobhan Mee
Director, Revenue Management
602-344-8463

Submitter : Mrs. Catherine Meeter **Date:** 09/14/2005

Organization : Sutter Health

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Re: Section IV, 2.c. Existing Device Categories. Sutter Health would like to comment on CMS's comment on page 42721 of the Federal Register in this section that 'this may entail the need to clarify or refine the short or long descriptors of the previous category.' I would like to point out to CMS that the description of HCPCS code C1713 is as follows: Anchor/screw for opposing bone to bone or soft tissue to bone (implantable). Literature published by CMS indicates that this code should be used in addition for plates, washers and nuts.I understand that you routinely do not make changes to descripions and that there is no current payment associated with this code. I am respectfully requesting that the long descriptor be enhanced because I believe that entities that use this code are not fully aware that it encompasses the plates, washers and nuts. If you were responsible for ensuring that this code was attached to the appropriate supplies at your facility and you just looked at the short or long description, you would never know that this code can be used for these items. CMS literature has clearly encouraged hopsitals to use codes for supplies where they exist and I believe a large population of hospitals are not using this code where they can for plates, washers and nuts. This change would be beneficial to all hospitals who operate under OPPS and does not seem to be too hard to accomplish if you just enhance the long description out on the website. The description should fully reflect what CMS wants it to encompass.

Submitter : Mrs. Catherine Meeter **Date:** 09/15/2005

Organization : Sutter Health

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Re: Section V, B. 3 - Proposed Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Status That Are Not Packaged. Sutter Health would like to comment on CMS's proposal to pay for drugs under OPPS using the ASP methodology. There are concerns that where the ASP info. does not exist that CMS will use 2004 hospital claims data, and with drug cost/price increases averaging 5 to 10% over the past two years, that the reimbursement would not be enough to cover the cost to replace these drugs. We would also like to know if the ASP could be calculated regionally instead of nationally.

Submitter : Mrs. Catherine Meeter

Date: 09/15/2005

Organization : Sutter Health

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Re: Section V, B. 5 Proposed Payment Changes for Drugs, Biologicals and Radiopharmaceutical Agents, MedPac Report on APC Payment Rate Adjustment of Specified Covered Outpatient Drugs - re: the proposal to establish three distinct C codes corresponding to APCs for drug handling categories to differentiate overhead costs for drugs and biologicals. Feedback from around my system indicates that this would be very problematic for our hospitals to automate this, thereby creating the need for manual processes to be put in place. Creating a manual process to ensure these codes are generated with each drug would be very onerous upon a hospital and not lend itself to accurate reporting nor cost effectiveness. Also, the categories created by CMS do not match the current categories that Sutter Health created for all our pharmacies to use that are currently reported together as one price in conjunction with the AWP of the drug. CMS also indicates they would want these codes to be generated for just separately payable drugs. That would be impossible to acomplish, i.e. do this for some drugs and not for others. It would radically change the way we charge, even if it could be accomplished. We strongly recommend against this proposal.

Submitter : Dr. James Carroll **Date:** 09/15/2005

Organization : Midstate Medical Center

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment.

CMS-1501-P-432-Attach-1.DOC

James W. Carroll, M.D.
Midstate Radiology Associates
Midstate Medical Center
435 Lewis Ave.
Meriden, CT 06451

The Honorable Mark McClellan
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
Room 445-G
200 Independence Avenue, S.W.
Washington, D.C. 20201

ATTN: FILE CODE CMS-1501-P

Re: Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates

Dear Dr. McClellan:

I am writing on behalf of the Midstate Medical Center on an issue of great importance to Medicare beneficiaries with cancer. Midstate Medical Center is a leading community hospital in central Connecticut, committed to providing expert cancer care. Positron emission tomography (PET) technology scans are an integral part of the Midstate Medical Center program to diagnose and manage patients with cancer. We are pleased that the Centers for Medicare and Medicaid Services (CMS) has recently proposed to expand cancer coverage for PET scans. We are concerned, however, that the proposed hospital outpatient payment rate for PET/CT scans is inadequate to cover hospital costs for this new technology.

The PET/CT scanner is the latest advance in oncology imaging which combines two state-of-the-art imaging modalities. PET is a highly sensitive technique that detects the metabolic signal from actively growing cancer cells in the body. The key to PET's effectiveness is that it provides physicians with information about the body's chemistry, cell function, and metabolism that anatomic imaging modalities such as CT and MRI are unable to provide. The PET scan does not provide the exact anatomic location of the signal in the body. CT provides high resolution anatomic information regarding the location, size, and shape of various lesions, however it cannot differentiate cancerous lesions from normal structures with the same accuracy as PET. The combined PET/CT scanner merges PET and CT images together, thereby more accurately identifying and localizing tumors in the body.

Last year, CMS in the Hospital Outpatient Rule decreased payment rates for PET scans from $1375 to $1150. This decreased rate has challenged our ability to provide

PET scans to medical beneficiaries. We applaud the CMS decision in the proposed rule to keep stable the payment rate for PET scans, thereby avoiding further constraints on providers' ability to offer this service.

We are concerned, however, about the proposed payment rate for PET/CT. We are in the process of arranging for mobile PET/CT services requested by our cancer center. PET/CT scan is the leading diagnostic imaging tool for managing patients with cancer. The proposed payment rate of $1250 is well below our cost for these scans. Without adequate reimbursement, beneficiary access to PET/CT will be limited.

I urge you to keep the hospital outpatient payment rates for PET scans stable and to increase the payment rate for PET/CT to represent true costs for hospitals.

Thank you very much for your attention. Please feel free to contact me with more information.

Very truly yours,

James W. Carroll, MD

Submitter : Dr. John Niparko **Date:** 09/15/2005

Organization : The American Otological Society

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

I am writing on behalf of the Council of The American Otological Society and wish to convey our concerns regarding the proposed payment rate for cochlear implant devices/systems (APC 0259). The American Otological Society represents over 300 senior specialists who provide ear and hearing care on a daily basis. For properly screened and counseled patients who are unable to enjoy the benefit of sound with hearing aids, the availability of the cochlear implant has been a lifeline.

If the CMS APC 0259 proposed reductions were adopted, payment levels for cochlear implantation would decline by 14%. Such a decline in Medicare payment, which is already well below actual cost for many hospitals, will substantially disrupt cochlear implant services to Medicare beneficiaries. As you are aware, cochlear implant reimbursement levels have experienced increases in CMS payment levels in recent years. These increments have helped to offset the losses experienced by implant programs by bringing reimbursement closer to actual costs. However, if enacted, APC 0259 would lower reimbursement to an untenable level. Please note that implant costs have increased for providers every single year since 2000.

Ready access is required for cochlear implantation to be effective in seniors. Follow-up care, mapping the device?s electronics and maintaining a well tuned, functional device is critical to ensuring optimal results. Typically, 4 to 8 visits are required in the first year after surgery and though this number lessens in subsequent years, that first year is critical to outcomes. If reimbursement cutbacks were to reduce access to services, seniors would be forced to travel longer distances for after-surgery care and less likely to be achieve optimal outcomes.

Access to cochlear implant services has been observed in several studies to carry measurable benefit to health-related quality of life. More, these benefits have been observed to yield cost-effectiveness ratings that place cochlear implantation of seniors in a highly favorable position in its value relative to other covered interventions. Cochlear implantation increases the independence of Medicare beneficiaries through self-sufficiency and maintaining social networks.

The American Otological Society requests that CMS substitute accurate external device cost data in recalculating the relative weight of APC 0259. We understand that if this were done, the APC payment would approximate $27,200 for the combined device- and hospital facility-cost of cochlear implantation. This would place reimbursement levels closer to estimated costs at many institutions which exceed $32,000.

Please let me know if I can provide further information.

Sincerely,

John K. Niparko MD (Johns Hopkins University)
President
The American Otological Society

CMS-1501-P-433-Attach-1.DOC

September 8, 2005

Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; CMS-1501-P; Device-Dependant APCs.

Dear Doctor McClellan:

I am writing on behalf of the Council of The American Otological Society and wish to convey our concerns regarding the proposed payment rate for cochlear implant devices/systems (APC 0259). The American Otological Society represents over 300 senior specialists who provide ear and hearing care on a daily basis. For properly screened and counseled patients who are unable to enjoy the benefit of sound with hearing aids, the availability of the cochlear implant has been a lifeline.

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Please let me know if I can provide further information.

Sincerely,

John K. Niparko MD (Johns Hopkins University)
President
The American Otological Society

Submitter : Mrs. Patricia Golden

Date: 09/15/2005

Organization : American Society for Apheresis

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment

CMS-1501-P-434-Attach-1.DOC

CMS-1501-P-434-Attach-2.PDF

CMS-1501-P-434-Attach-3.DOC

THERAPEUTIC APHERESIS

A Guide to Billing and Securing Appropriate Reimbursement 2005 Edition

The American Society for Apheresis would like to thank and recognize the members of its Public Affairs Committee for their participation in the development of this Guide:

Chairperson: Chester Andrzejewski, PhD, MD

Matthew Coleman, MD

Patricia Jost Golden, RN, HP(ASCP)

Irene Zielinski, RN, HP(ASCP)

Robert Weinstein, MD

Prepared by:

Keith Berman, MPH, MBA
Health Research Associates
kberman@sbcglobal.net

The American Society for Apheresis has participated in preparing this guide, which may help you communicate more effectively with your billing staff about:

- Use of billing codes – the "language" of insurance claims and communications – to more accurately bill payers for your services
- How insurance billing and payment works in different treatment settings for the types of therapeutic apheresis procedures you perform

We hope you find this guide to be a useful tool as you work to minimize and resolve problems which may arise with insurance coverage or payment for your therapeutic apheresis services.

We would like to acknowledge the generous support of GAMBRO BCT, Inc. in providing a grant for the research and development of this guide.

Important – Please Note:

The information provided in this guide is for illustrative purposes only, and does not constitute billing, reimbursement or legal advice. Neither the American Society for Apheresis nor any of its members or supporters makes any representation or warranty concerning this information or its completeness, accuracy or timeliness. No entity involved in the preparation of this guide makes any representation about the likelihood of success in obtaining insurance coverage or reimbursement for any service.

It is solely the responsibility of the provider to determine and submit appropriate codes, charges and other documentation in claims for services rendered.

Contents

The Insurance Billing Process

As a physician or hospital provider of therapeutic apheresis services, you rely on payment from a variety of public and commercial insurers, which present a wide range of coverage policies and payment methods.

Insurance **coverage** of therapeutic apheresis procedures merits separate discussion in later sections of this guide.

To secure appropriate **payment**, your billing staff must assure that the insurance claim is complete and accurate. In certain instances, the claim must be customized to conform with the requirements of a particular insurer, or to alert that insurer to a contractual agreement.

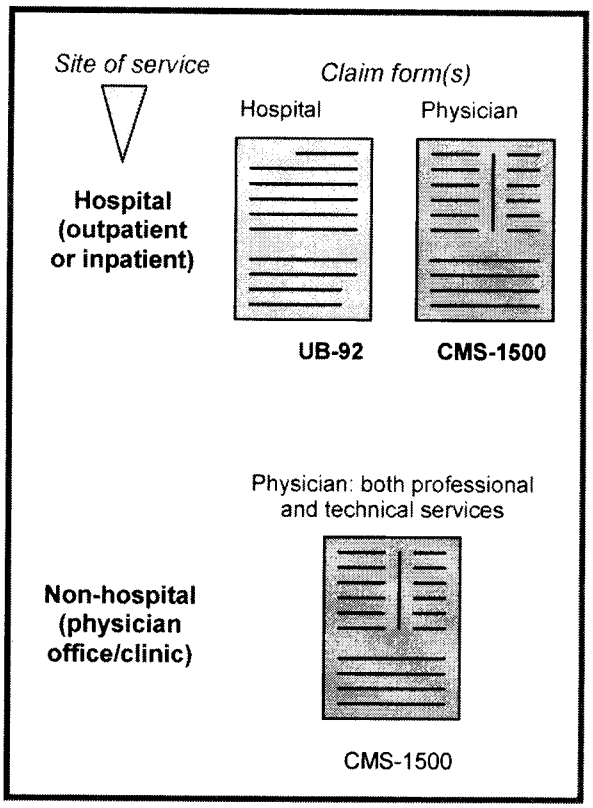
The mechanics of insurance billing process for apheresis services can be subdivided on the basis of:

- **The treatment setting** in which the service is performed (hospital vs. physician office/physician-directed clinic);
- **The entity** which is submitting a service claim (physician or hospital).

A therapeutic apheresis procedure conducted in the hospital inpatient or outpatient setting generally involves separate submission of ***two*** claim forms: the **CMS-1500*** by the **physician** personally overseeing the procedure and the **UB-92** by the **hospital** which provided the technical service itself.

When the procedure is performed in a physician office or physician-directed clinic setting, only a ***single*** CMS-1500 claim form is required.

Claim Forms Submitted Depend on the Site of Service



The two "universal" insurance claim forms:

UB-92	Hospital claim form (Appendix A)
CMS-1500	Physician office/clinic claim form (Appendix B)

* Formerly known as the "HCFA-1500" claim form.

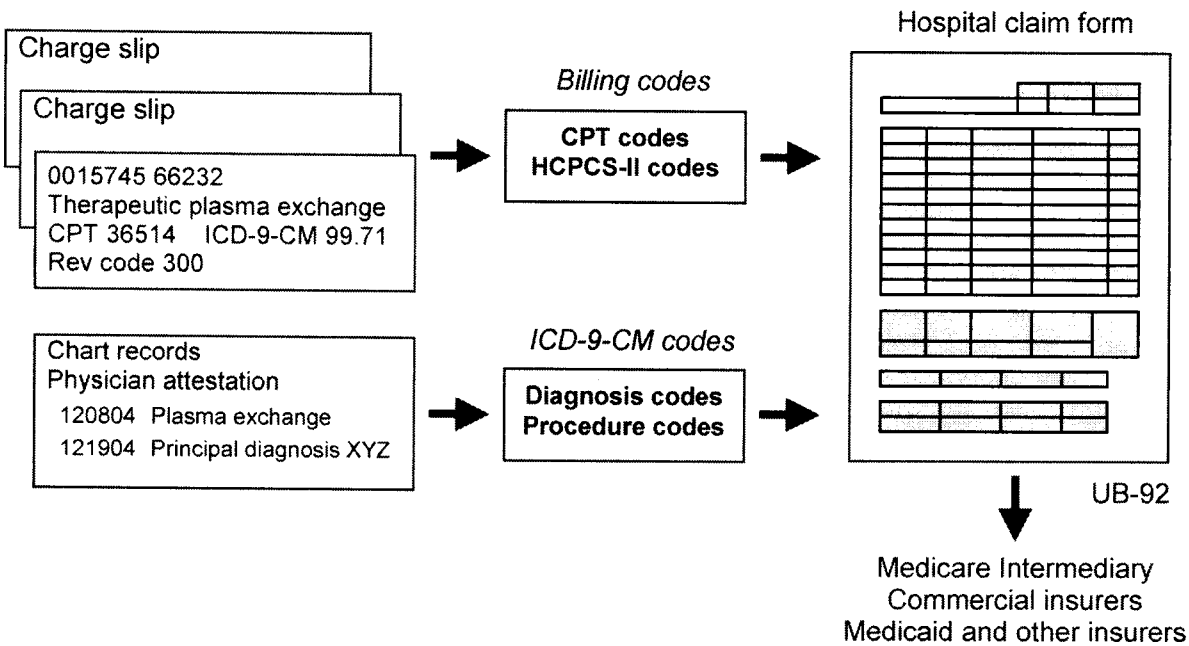
Hospital Billing on the UB-92 Claim Form

The hospital's "**charge master**" contains a database of thousands of services and items.

Each of these services and items is assigned not only a **charge** but an associated **CPT**[1] or **HCPCS**[2] **Level II billing code** to identify it for the insurer, and a three-digit **revenue code** which allows it to be grouped by type of service, or by a specific operating department in the hospital.

Every time a procedure is performed or an item is used for a hospital inpatient or outpatient, a paper or electronic "**charge slip**" is generated and sent to the billing department to be added to the patient's claim.

Separately, both input from the attending physician and examination of patient chart notes enables billing staff to enter **diagnosis codes** and applicable **procedure codes**.



Key billing codes used for the UB-92 hospital claim form

CPT codes: identify billable procedures, physician services and hospital laboratory services

HCPCS Level II codes: identify drugs, biologicals, blood products, durable medical equipment (DME), certain supplies and selected procedures

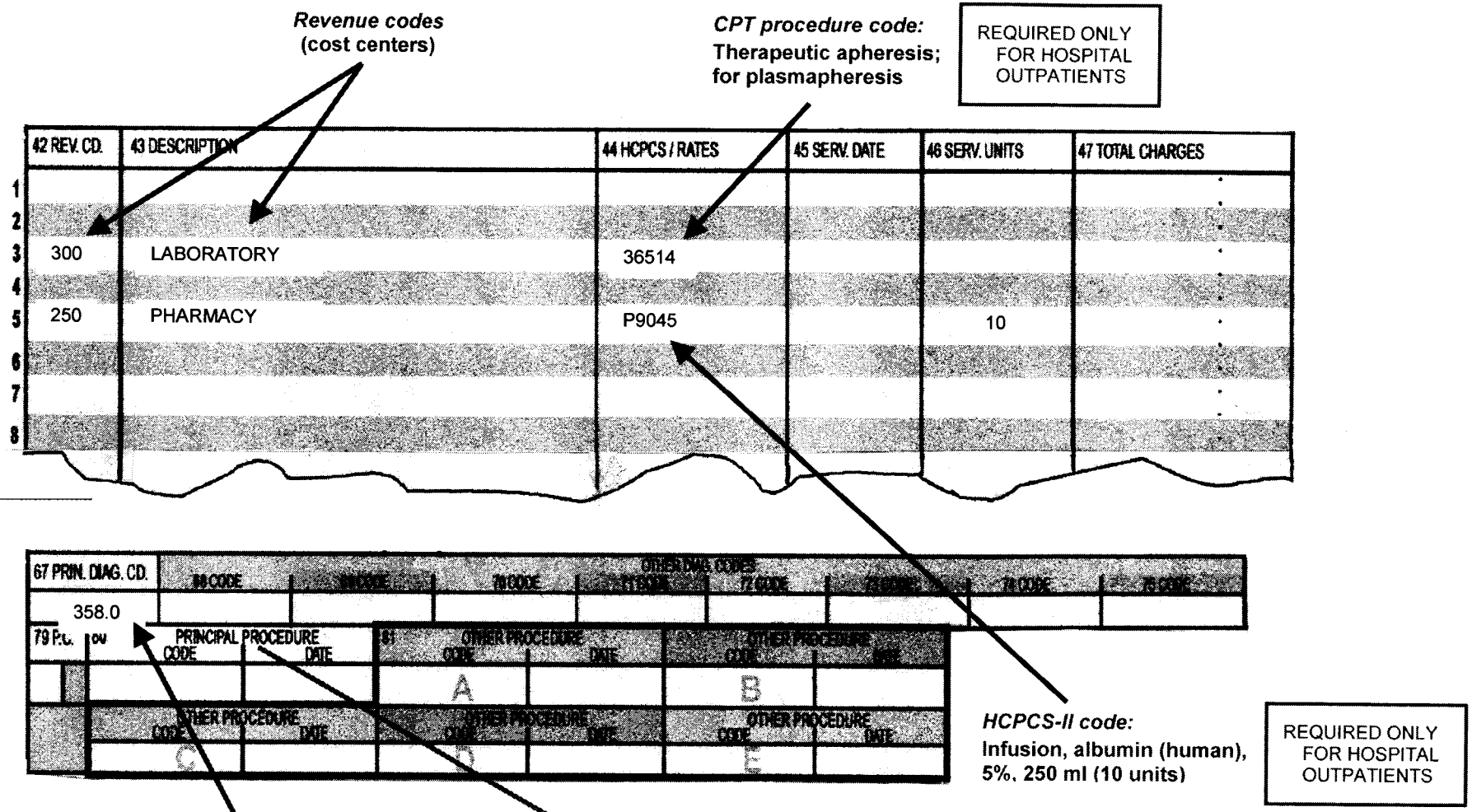
ICD-9-CM[3] diagnosis codes: a system of codes identifying related diseases and injuries (always use complete coding; code a 5th digit when applicable)

ICD-9-CM[3] procedure codes: a system of codes identifying specific hospital-based procedures

Revenue codes: group similar types of hospital services and items by type of service

[1]Current Procedural Terminology: CPT© 2005. American Medical Association. All rights reserved.
[2]Healthcare Common Procedure Coding System.
[3]International Classification of Diseases, 9th Revision, Clinical Modification.

Sample Coding of a Hospital Therapeutic Apheresis Claim



Physician Billing on the CMS-1500 Claim Form

Treatment-related information required for insurers to process claims from physicians and physician-directed clinics prominently includes:

For apheresis procedures, the **place of service code** (Field 24B) is *extremely important*

Enter

11 Physician's office or non-hospital MD-directed clinic setting

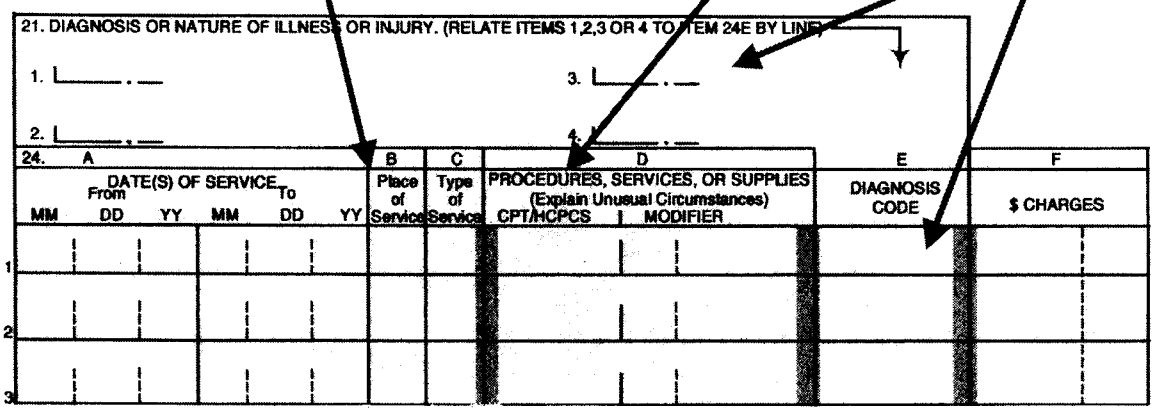
22 Hospital outpatient setting

21 Hospital inpatient setting

CPT coded procedures or services *and*

HCPCS Level II coded blood products, biologicals, drugs, DME

ICD-9-CM diagnosis codes specifying the diagnosis that "relates" to each CPT-coded service or HCPCS- coded item



NOTE: The physician can separately bill an **Evaluation & Management (E & M) code** for a history and physical exam to determine the appropriateness of the therapeutic apheresis procedure.

Key billing codes used for the CMS-1500 physician claim form

CPT codes: identify billable procedures and services

HCPCS Level II codes: identify drugs, biologicals, blood products, durable medical equipment (DME), certain supplies and selected procedures

ICD-9-CM diagnosis codes: a system of codes identifying related diseases and injuries (always use complete coding; code a 5th digit when applicable)

Place of Service codes: informs insurer where the apheresis procedure was performed; dictates payment for global service or professional component only

Codes Commonly Used to Bill Apheresis Services

Procedure codes

CPT procedure codes	*ICD-9-CM procedure codes and nomenclature*
36511 **Therapeutic apheresis**; for white blood cells	99.72 Therapeutic leukopheresis (therapeutic leukocytapheresis)
36512 for red blood cells	99.73 Therapeutic erythrocytapheresis (therapeutic erythropheresis)
36513 for platelets	99.74 Therapeutic plateletpheresis
36514 for plasmapheresis	99.71 Therapeutic plasmapheresis
36515 with extracorporeal immunoadsorption and plasma reinfusion	99.76 Extracorporeal immunoadsorption
36516 with extracorporeal selective adsorption or selective filtration and plasma reinfusion	99.79 Therapeutic apheresis, other
36522 Photopheresis, extracorporeal	99.88 Therapeutic photopheresis

38205 Blood-derived hematopoietic stem cell harvesting for transplantation; allogeneic	99.79 Therapeutic apheresis, other
38206 autologous	99.88 Therapeutic apheresis, other

Common revenue codes used by hospitals on UB-92 claim form:

Revenue code	*Descriptor*
300 (309)	Laboratory – General Classification (Other Laboratory)
510 (519)	Clinic – General Classification (Other Clinic)
20X	Intensive Care (200 – General; 202 – Medical; 209 – Other)
390 (399)	Blood Storage and Processing – General Classification (Other BSP)
280 (289)	Oncology – General Classification (Other Oncology)
940 (949)	Other Therapeutic Services – General Classification (Other Therap Services)

Diagnosis codes: see "focus" sections for specific therapeutic apheresis procedures.

Insurance Coverage for Therapeutic Apheresis Services

While our "focus" sections address insurance coverage issues for specific apheresis procedures, below are general principles which broadly apply to coverage determination:

- The **scope of coverage** – all conditions determined to be medically necessary – **may vary by insurer**, depending on their methodology and rigor in establishing and updating their coverage policies.

  Some insurers use clinical consultants to help define or refine coverage policies, others adapt Medicare coverage policies, and still others contract the services of third party administrators (TPAs). Increasingly, formal **technology assessments** influence coverage policy-making (see below).

- Specific ICD-9-CM coded diagnoses that support "medical necessity are often covered *only* if the patient meets additional diagnostic or laboratory criteria.

  Example: XYZ plan covers TPE for severe cases of Guillain-Barré syndrome (Grades 3-5), and for polymyositis only after the provider documents that the patient is unresponsive to conventional therapy.

- **Preauthorization** (physician) or **precertification** (hospital) is commonly required by commercial insurers (HMOs, PPOs, indemnity plans, point-of-service plans) and Medicaid programs *prior* to performing therapeutic apheresis procedures.

  To secure this prior authorization, the insurer may specify documentation required for review by a case manager or medical director. This may include a detailed patient history, examination, treatment and/or laboratory records. Appendix 1 provides a guideline for preparing what is commonly referred to as a "Letter of Necessity" (LON) or "Statement of Medical Necessity" (SOMN) to accompany supportive medical and lab records.

- Medicare Intermediaries (hospital) and Carriers (physician) do not require prior authorization, but *do* typically require documentation of medical necessity for coverage and payment of the initial submitted claim. For outpatient services, Medicare contractors use **National Coverage Policies** or create their own **Local Medical Review Policies (LMRPs)** to make coverage determinations.

- In some instances, coverage may be determined on an **Individual consideration basis**, particularly where published clinical evidence is suggestive (e.g. successful case reports or small patient studies) but inconclusive or controversial.

Examples of Formal Technology Assessments Which Influence Coverage Policies for Therapeutic Apheresis Services

American Society for Apheresis. Special Issue: Clinical Applications of Therapeutic Apheresis. *J Clin Apheresis* 2000; 15:1-159.

The Technology Evaluation Center: Lipid Apheresis in the Treatment of Severe, Refractory Hypercholesterolemia. May 1999 (Vol. 14, No. 5). Chicago: Blue Cross and Blue Shield Association.

The Technology Evaluation Center: Extracorporeal Photopheresis for Graft-Versus-Host Disease. November 2001 (Vol. 16, No. 9). Chicago: Blue Cross and Blue Shield Association.

Medicare Payment in the Hospital Outpatient Setting

Medicare groups hospital outpatient procedures involving similar types and resources into **ambulatory payment classifications (APCs)** for purposes of payment.

With the special exception of plasmapheresis (CPT 36514), just two APCs apply for all therapeutic apheresis and stem cell collection procedures:

CPT/HCPCS and Description	*2005 APC*	*2005 Payment Rate*	
36511 Therapeutic apheresis; for white blood cells **36512** for red blood cells **36513** for platelets **38205** Blood-derived hematopoietic stem cell harvesting for transplantation; allogeneic **38206** autologous	**0111**	**$725.16**[1]	
36514 Therapeutic apheresis; for plasmapheresis + ***Quantity of albumin or FFP used as a replacement fluid, e.g.:*** **P9045** Infusion, albumin (human), 5%, 250 ml *[patient requires 10 units]*	**0111** + **0963**	**$725.16**[1] + $60.54 x 10 = **$605.40**	**$1,330.56**[1]
36515 Therapeutic apheresis; with extracorporeal immunoadsorption and plasma reinfusion[2]	**0111**	**$725.16**[1,4]	
36516 Therapeutic apheresis; with extracorporeal selective adsorption or selective filtration and plasma reinfusion[3] **36522** Photopheresis, extracorporeal	**0112**	**$2,127.26**[1]	

[1]Adjusted to reflect geographic wage variations using the "hospital wage index;" adjustment is applied to labor portion. *Federal Register*, Vol. 69, No. 3, November 15, 2004.

[2]Currently applies to protein A immunoadsorption therapy (*Prosorba*®, Fresenius HemoCare).

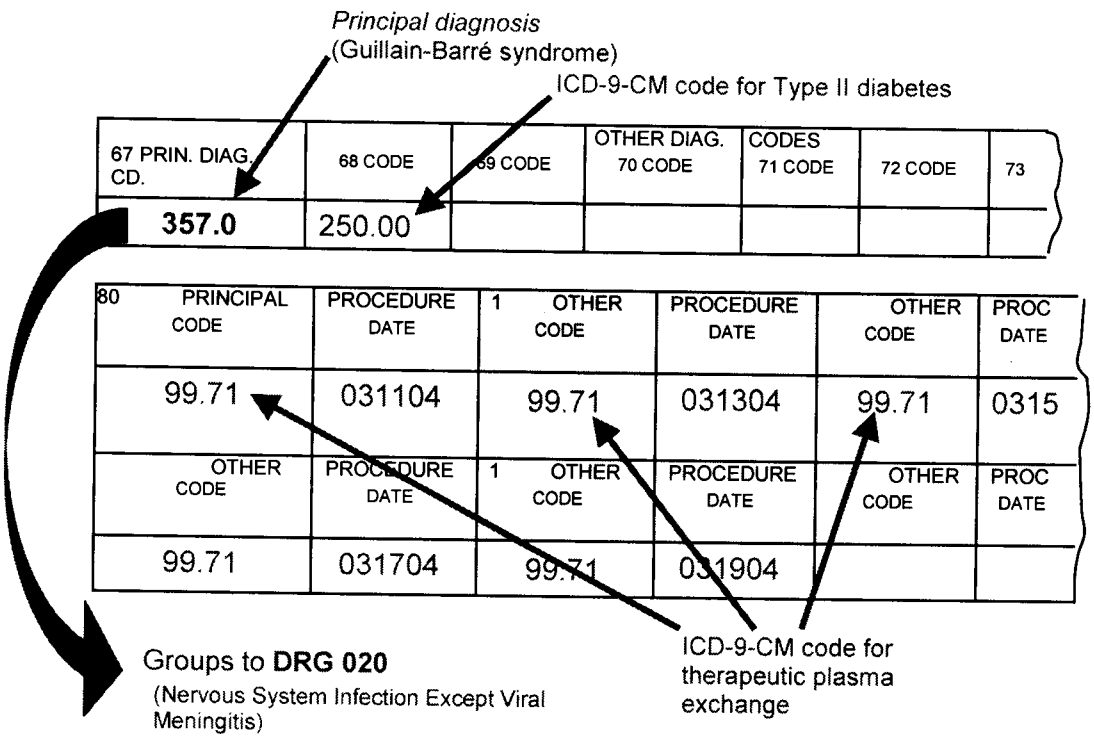
[3]Currently applies to LDL apheresis (*Liposorber*®, Kaneka America and *HELP System*, B. Braun Medical).

[4] Prior to 2005, this procedure was assigned to APC 0112; efforts are in progress to return it to APC 0112; see "Focus on Extracorporeal Immunoadsorption (*Prosorba*)" on page 20.

Medicare Payment in the Hospital Inpatient Setting

Since 1983, Medicare has paid for inpatient stays using a set of more than 500 **Diagnosis-Related Groups (DRGs)**. While some DRGs are actually assigned on the basis of a major operating room procedure, the DRGs for inpatient stays which involve a therapeutic apheresis are usually driven by the **principal diagnosis**, e.g. the diagnosis that accounted for the patient's hospitalization.

Below is an example of a claim submitted to the hospital's local Medicare Intermediary, which illustrates how a particular DRG is assigned on the basis of specific submitted codes. This particular patient was admitted with Guillain Barré syndrome[1] and received a total of five therapeutic plasma exchange (TPE) procedures over her hospital stay.



DRG 020 also applies for Medicare hospitalizations for nearly 50 other principal diagnoses, including various meningitis and encephalitis conditions. Your institution's payment rate is calculated by CMS in accordance with such factors as your local wage index, enrollment in any graduate medical education program(s) and uncompensated care burden.

Interestingly, chronic inflammatory demyelinating polyradiculoneuropathy, or CIDP (ICD-9 356.9) groups the hospitalization to either DRG 018 or DRG 019 (Cranial and Peripheral Nerve Disorders With and Without Complications/Comorbidities, respectively). Payment rates for DRG 018 and 019 fall well under that for DRG 020, even if the patient happens to be hospitalized for an entire initial course of 4 to 6 plasma exchanges.

[1] Also referred to as acute inflammatory demyelinating polyradiculoneuropathy (AIDP).

Medicare Payment in the Hospital Inpatient Setting – continued

Below are examples of DRGs commonly assigned for Medicare hospital inpatient stays in which therapeutic plasma exchange has been used to treat the principal diagnosis.

Principal Diagnosis	*ICD-9-CM*	*DRG*	*Relative weight*
Myasthenia gravis	358.0	**012**	0.9136
Acute glomerulonephritis with rapidly progressive glomerulonephritis lesions Chronic glomerulonephritis with rapidly progressive glomerulonephritis lesions	580.4 582.4	**331**	1.0595
Thrombotic thrombocytopenic purpura	446.6	**240**	1.3500
Cryoglobulinemia	273.2	**539**	3.3809
Guillain Barré syndrome (AIDP)	357.0	**020**	2.8318
CIDP with complications/comorbidities	356.9	**018**	0.9919
CIDP w/o complications/comorbidities	356.9	**019**	0.7048

After multiplying the "relative weight" for an assigned DRG by standard "base payment rate" set each year by CMS, your institution's payment rate is customized on the basis of several variables, prominently including local wage rates, your uncompensated care burden and enrollment in any graduate medical education programs.

You can learn the payment rate for a particular DRG of interest at your institution by inquiring with your financial services or other appropriate administrative staff member.

Two points in particular are worth noting:

1. Your DRG-based payment rate for each of these hospitalizations potentially involving use of TPE is **independent of the number of TPE procedures** provided over the course of the stay; and
2. The DRG, and therefore the payment rate, is usually driven by the patient's **principal diagnosis**. It is not influenced by the use of TPE, administration of drugs or biologicals like IVIG, or by other resources required over the course of the stay.

As DRG assignments are based on documentation in the hospital chart, it is important that all medical records:

- Be comprehensive and complete
- Include all diagnoses, procedures, complications and comorbidities
- Be legible

This attention to accuracy and detail facilitates proper coding, thereby maximizing the likelihood of appropriate DRG assignment.

Expanded Medicare Payment for Office-Based Plasma Exchange, Immunoadsorption, LDL Apheresis and Photopheresis

Effective January 1, 2005, Medicare has newly established payment rates for the technical service components of **therapeutic plasma exchange** (CPT 36514), **immunoadsorption**[1] (CPT 36515) and **LDL apheresis** (CPT 36516) procedures in the office-based setting.[2] The full 2005 payment rates will reflect (1) physician work, (2) procedural overhead including all practice expenses and (3) a small allocation for malpractice insurance.

Medicare had earlier defined a national payment rate, based on assigned **relative value units (RVUs)**, for the technical component ("practice expense") of extracorporeal photopheresis (CPT 36522) performed in the office-based setting.

The same diagnosis-based coverage policies apply for procedures performed in physician-directed clinics as hospital outpatient departments.

Calendar 2005: Practice Expense Relative Value Units (RVUs) Now Defined for Therapeutic Apheresis Services in the Physician Office-Based Setting

CPT	Description	MD work RVUs	Non-facility PE[3] RVUs	Malpractice RVUs	Non-facility total
36514	Apheresis, plasma	1.74	**16.97**	0.08	**18.79**
36515	Apheresis, adsorption	1.74	**66.30**	0.08	**68.12**
36516	Apheresis, selective	1.22	**84.05**	0.08	**85.35**
36522	Photopheresis	1.67	**32.37**	0.13	**34.17**

The physician payment rate is based on the conversion factor (CF) which applies in his or her locality. The national average CF for 2005 is **$37.8975**. It tends to be marginally higher or lower in high and low wage rate localities, respectively.

Example: U.S. average 2005 Medicare payment rate for an office-based TPE procedure is $37.8975 x 18.79 RVUs = **$712.09**.

Payment for albumin replacement solution. On a quarterly basis beginning January 1, 2005, Medicare is publishing its "payment allowance limits" for human albumin products, including (1) Albumin, 5%, 250 ml (**P9045**), (2) Albumin (human), 25%, 50 ml (**P9047**) and other albumin and PPF products. These standard payment rates are available either from the CMS website or your local Carrier. Commercial insurers should be billed with the same HCPCS code and your charge.

When a procedure is performed in the **hospital setting**, the physician again bills relevant professional services. The local Medicare Carrier's fee schedule will reflect the same physician work and malpractice expense RVUs, together with nominal **"facility practice expense RVUs"** (facility = hospital). These facility PE RVUs range from 0.48 to 0.96 RVU, depending on the specific procedure. Total 2005 RVUs range from **1.78 to 2.76**.[2]

[1]The *Prosorba*® protein A immunoadsorption column technology (Fresenius Hemocare) is currently the only licensed procedure which codes to CPT 36515.

[2]*Federal Register*, Vol. 69, No. 219, November 15, 2004, pp. 66502-66503.

[3]Non-facility PE = non-hospital (physician office or physician-directed clinic) practice expense.

Payment Policies by Commercial Insurers

Hospital

Outpatient Setting:

The overwhelming majority of claims for hospital outpatient services are paid on the basis of:

- A **set rate schedule** for CPT- and HCPCS-coded services/products *or*
- A **percentage of the hospital's submitted charges**

In both scenarios, each TPE service is directly reimbursed by the payer, on terms pre-negotiated between the insurer and the hospital.

Inpatient Setting:

Per diems (fixed payment per hospitalization day) represent the predominant payment mechanism for hospital stays required to manage medical conditions.*

The costs of TPE are generally not reflected in the per diem payment; this applies as well to use of other costly resources (e.g. IVIG, lab tests). "Outlier" provisions often provide additional reimbursement when overall costs exceed a certain threshold.

Physician

Hospital Inpatient or Outpatient Setting

Without regard to whether the procedure was performed on a hospital outpatient or inpatient, the physician's separately billed professional services are paid in accordance with the insurer's **allowable amount** (or "allowable charge") for CPT 36522.

Some commercial insurers set their "allowables" based on actual charges in the locality they serve. Others may pay the lesser of the physician charge or a rate schedule amount based on RVUs in the Medicare Physician Fee Schedule.

In the procedure note, the physician should document that he/she (1) reviewed and evaluated pertinent clinical and lab data to make the decision to treat the patient on the day in question, **(2)** saw and evaluated the patient during the procedure and **(3)** remained available to respond in person to emergencies or other situations requiring his/her presence throughout the duration of the procedure (*ASFA Newsletter*, 20[3], Spring 2001).

Physician Office or Physician-Directed Clinic Setting

On January 1, 2005, Medicare published newly established **relative value units** (RVUs) for the "nonfacility practice expenses" applicable to **TPE** (CPT 36514), **immunoadsorption with plasma reinfusion** (CPT 36515), **selective adsorption or filtration with plasma reinfusion** (CPT 36516) and/or **extracorporeal photopheresis** (CPT 36522).

Many commercial insurers may elect to base their payment rates on these new RVUs. Others will set payment rates on the basis of submitted charges or some other basis. Until these apheresis services become commonplace, some physicians can expect a back-and-forth process of rate negotiation with commercial insurers that agree to cover therapeutic apheresis procedures for their patients in the physician office or clinic setting.

Focus on Therapeutic Plasma Exchange (TPE)

Diagnosis Coding and Coverage

Therapeutic plasma exchange (TPE) (CPT 36514) has been shown to be effective either as primary, adjunctive or supportive therapy for a number of disorders, including but not limited to hematological, neurological, renal and autoimmune disorders.

The benefits of TPE for many other proposed applications remain uncertain or unproven. These include ASFA's Category III disorders for which "controlled trials have produced conflicting results or for which anecdotal reports are too few or too variable to support an adequate consensus." (*J Clin Apheresis* 2000; 15:1) (see Appendix 2; page 28).

Coverage of some diagnoses can be inconsistent from one insurer to the next, underscoring the importance of securing preauthorization for TPE therapy. Particularly important is to learn what **conditions for coverage** apply for a specific diagnosis.

Below are selected diagnoses for which TPE is commonly covered, variously as first-line therapy, adjunctive therapy, or as "last resort" or salvage therapy:*

Diagnosis	*ICD-9-CM*
Guillain-Barré syndrome	357.0
Lambert-Eaton myasthenic syndrome	358.1
Myasthenia gravis	358.0
Macroglobulinemia (incl. Waldenstrom's)	273.3
Glomerulonephritis w/anti-glomerular BM antibodies	583.89
Rapidly progressive glomerulonephritis (unspecified)	583.4

Diagnosis	*ICD-9-CM*
CIDP	356.9
2° thrombocytopenia; post-transfusion purpura (PTP)	287.4
Sydenham's chorea	392.9
Thrombotic thrombocytopenic purpura (TTP)	446.6
Other paraproteinemias (e.g. cryoglobulinemia)	273.2
Systemic lupus erythematosis	710.0

Therapeutic Cytapheresis:
Major Clinical Applications are Few and Straightforward

Procedure	*Commonly treated diagnoses*	*ICD-9-CM*
Leukocytapheresis (CPT 36511)	Leukocytosis	**288.8**
Erythrocytapheresis[1] (CPT 36512)	Sickle-cell anemia Polycythemia; erythrocytosis	**282.6X**[2] **289.6**
Plateletpheresis (CPT 36513)	Thrombocytosis, essential	**289.9**

[1]with red cell exchange for sickle-cell anemia
[2]predominantly sickle-cell crisis (202.62)

*ICD-9-CM codes for diseases designated by ASFA and AABB as Category I, II and III applications of TPE, cytapheresis and other specialized procedures appear in Appendix 2.

Medicare's Coverage Policy for Therapeutic Plasma Exchange

While now outdated (last updated in 1992), Medicare Carriers and Intermediaries reference the policy below to make coverage determinations for claims which include outpatient TPE.

Commercial insurers may or may not reference this coverage policy in making their own coverage determinations. For ASFA/AABB clinical guidelines, see Appendix 2.

Publication Number: 100-3
Medicare Coverage Manual Sect. 110.14 (Coverage Issues Manual §35-60)
Effective Date: 7/30/1992

Benefit Category:
Incident to a physician's professional Service
Outpatient Hospital Services Incident to a Physician's Service
Physicians' Services

Apheresis (also known as pheresis or therapeutic pheresis) is a medical procedure utilizing specialized equipment to remove selected blood constituents (plasma, leukocytes, platelets, or cells) from whole blood. The remainder is retransfused into the person from whom the blood was taken.

For purposes of Medicare coverage, apheresis is defined as an autologous procedure, i.e., blood is taken from the patient, processed, and returned to the patient as part of a continuous procedure (as distinguished from the procedure in which a patient donates blood preoperatively and is transfused with the donated blood at a later date).

Indications and Limitations of Coverage. Apheresis is covered for the following indications:

- Plasma exchange for acquired myasthenia gravis;
- Leukapheresis in the treatment of leukemia;
- Plasmapheresis in the treatment of primary macroglobulinemia (Waldenstrom);
- Treatment of hyperglobulinemias, including (but not limited to) multiple myelomas, cryoglobulinemia and hyperviscosity syndromes;
- Plasmapheresis or plasma exchange as a last resort treatment of thromobotic thrombocytopenic purpura (TTP);
- Plasmapheresis or PE in the last resort treatment of life threatening rheumatoid vasculitis;
- Plasma perfusion of charcoal filters for treatment of pruritis of cholestatic liver disease;
- Plasma exchange in the treatment of Goodpasture's Syndrome;
- Plasma exchange in the treatment of glomerulonephritis associated with antiglomerular basement membrane antibodies and advancing renal failure or pulmonary hemorrhage;
- Treatment of chronic relapsing polyneuropathy for patients with severe or life threatening symptoms who have failed to respond to conventional therapy;
- Treatment of life threatening scleroderma and polymyositis when the patient is unresponsive to conventional therapy;
- Treatment of Guillain-Barré Syndrome; and
- Treatment of last resort for life threatening systemic lupus erythematosus (SLE) when conventional therapy has failed to prevent clinical deterioration.

Settings. Apheresis is covered only when performed in a hospital setting (inpatient or outpatient) or in a nonhospital setting, e.g., a physician directed clinic when the following conditions are met:

- A physician (or a number of physicians) is present to perform medical services and to respond to medical emergencies at all times during patient care hours;
- Each patient is under the care of a physician; and
- All nonphysician services are furnished under the direct, personal supervision of a physician.

Focus on Therapeutic Plasma Exchange – continued

Payment: Hospital Outpatient

Commercial insurers. Payment for the technical component of a TPE procedure is most commonly based either on a **fixed percentage of the hospital's submitted charge** or the insurer's **fee schedule amount**.

It is very important to consistently itemize – or "capture" – all drugs, IV fluids and supply items used in each TPE procedure, so they are all posted as charges on the claim.

Payment for the **physician's professional services** associated with hospital-based procedures is usually based on the insurer's allowable rate, which in turn is often tied to the 1.74 physician work RVUs defined for this service in 2005.

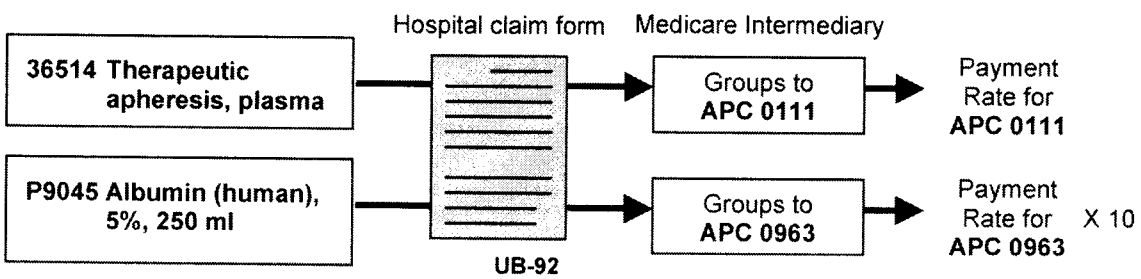
Medicare. The Hospital Outpatient Prospective Payment System (HOPPS) assigns:

APC **0111** (Blood Product Exchange) for outpatient TPE claims coded with **CPT 36514**

+

An APC corresponding to **the blood or plasma product** replacing autologous plasma

Earlier (see "Medicare Payment in the Hospital Outpatient Setting") we reviewed a case example involving TPE (**CPT 36514**) with infusion of 10 units (250 ml size) of 5% human albumin: the HCPCS Level II code for 5% 250 ml albumin (**P9045**) corresponds to APC **0963**, whose 2005 payment rate is $60.54 per unit:



Other delivery forms of albumin (or plasma protein fraction) and fresh frozen plasma (FFP) may be administered or transfused as part of a TPE procedure; each groups to an APC, for which multiple "units" can be paid:

Product	*HCPCS-II*	*APC*
Albumin, 25%, 50 ml	P9047	**0965**
PPF, 5%, 250 ml	P9048	**0966**
Cryo-reduced plasma	P9044	**1009**
FFP, frozen ≤8 hours	P9017	**0955**

See **Appendix 3** for a list of 2004 HCPCS codes for billing albumin, FFP and blood components

The same dual payment methodology applies for outpatient **red cell exchange**:

P9016 RBCs, leukoreduced

↓

APC 0954

↓

Payment rate X Units

Focus on Therapeutic Plasma Exchange – continued

Payment: Hospital Outpatient (continued)

Below again are the two APCs which correspond to the nine therapeutic apheresis and stem cell harvesting procedures. Note that the descriptors for these APCs are confusing and potentially misleading. It is best to refer to these APCs solely by their numbers.

CPT and Description		
36511	Therapeutic apheresis; for white blood cells	**APC 0111** Blood product exchange
36512	for red blood cells	
36513	for platelets	
36514	**for plasmapheresis**	
38205	Blood-derived hematopoietic stem cell harvesting for transplantation; allogeneic	
38206	autologous	
36515*	Therapeutic apheresis; with extracorporeal immunoadsorption and plasma reinfusion	
36516	Therapeutic apheresis; with extracorporeal selective adsorption or selective filtration and plasma reinfusion	**APC 0112** Apheresis, Photopheresis, and Plasmapheresis
36522	Photopheresis, extracorporeal	

**NOTE: Prior to 1/1/2005, CPT 36515 was assigned to APC 0112. Several parties are working with CMS to restore it to APC 0112. Check with your Medicare Intermediary for CPT 36515 payment status.*

Payment: Hospital Inpatient

Commercial insurers. The costs of TPE may be subsumed under a flat **per diem** payment rate negotiated between the hospital and the insurer; there is no separate payment for TPE in this circumstance. Less frequently, TPE may be subsumed under a fixed, prospectively determined payment rate for the entire hospital stay, or paid on the basis of a negotiated percentage of charges.

Medicare. Please refer to the section titled **"Medicare Payment in the Hospital Inpatient Setting,"** which presents an example of a Guillain-Barré patient treated with TPE.

Payment: Physician Office or Physician-Directed Clinic

Please refer to the guide section titled **"Expanded Medicare Payment for Office-Based Plasma Exchange, Immunoadsorption, LDL Apheresis and Photopheresis"** on page 10.

Focus on Extracorporeal Photopheresis (ECP)

Diagnosis Coding

Extracorporeal photopheresis (ECP) is indicated by the FDA for treatment of **cutaneous T cell lymphoma (CTCL)**, which is a general term for certain closely related malignancies:

Mycosis fungoides	**202.1**
Sézary's disease	**202.2**

Other non-indicated clinical applications for which ECP is used include:

Graft-versus-host disease (GVHD)	**996.85**
Post-heart transplant	**V42.1**
Post-lung transplant	**V42.6**
Post-renal transplant	**V42.0**

The diagnosis code must be entered on all applicable claim forms.

CTCL: 5th Digit Subclassifications

To more accurately specify the diagnosis, the physician can add a 5th digit to add to mycosis fungoides (201.1) or Sézary's disease (202.2):

0 unspecified or extranodal/solid organ sites
1 lymph nodes of head, face, and neck
2 intrathoracic lymph nodes
3 intra-abdominal lymph nodes
4 lymph nodes of axilla upper limb
5 lymph nodes of inguinal region/lower limb
6 intrapelvic lymph nodes
7 spleen
8 lymph nodes of multiple sites

Example: **202.26** represents Sézary's disease with splenic involvement

Procedure coding

CPT 36522	Physicians – CMS-1500 Hospitals (Outpatient) – UB-92
ICD-9-CM 99.88	Hospitals (Inpatient) – UB-92

Coverage

Medicare and most commercial insurers cover ECP for **palliative treatment of skin manifestations of CTCL** in patients who have failed to adequately respond to conventional therapy.

While Medicare's coverage policy expressly limits ECP coverage to this indication (see below), there are reports of "individual consideration" coverage of its use in treatment-refractory **graft-versus-host disease (GVHD)** by individual local Medicare contractors (Fiscal Intermediaries).

Many commercial insurers either formally cover ECP for use in GVHD or review cases for coverage on an individual consideration basis. Preauthorization or precertification for a planned series of treatments should always be secured from the primary and, as applicable, secondary insurer.

Medicare Coverage Policy for Extracorporeal Photopheresis*

Extracorporeal photopheresis is covered by Medicare only when used in the palliative treatment of the skin manifestations of CTCL that has not responded to other therapy.

*Coverage Issues Manual §35-88

Focus on Extracorporeal Photopheresis – continued

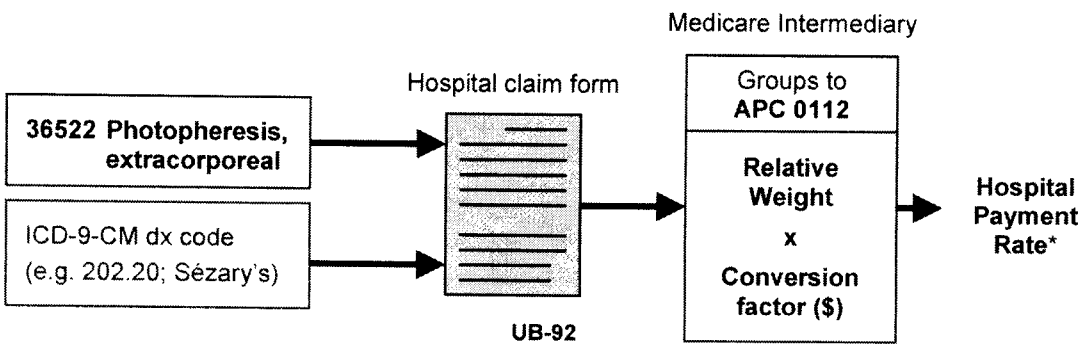
Payment: Hospital Outpatient

Commercial insurers. Payment for the technical component of an ECP procedure is most commonly based on a **fixed percentage of the hospital's submitted charge** or the insurer's **fee schedule amount**. Periodically there may be a **negotiation** between the institution and the insurer to arrive at a mutually acceptable payment rate.

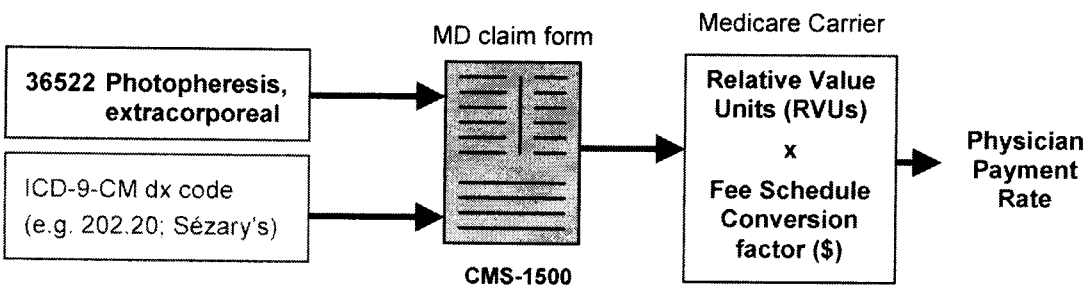
For bone marrow or stem cell transplant patients, many insurers negotiate a **global case rate** which includes all hospital (and often physician) services provided over the first 6-12 weeks of outpatient treatment. Thus, unless stipulated otherwise, ECP services to treat GVHD during that global period would be included in that global case rate. Subsequent to the global period, ECP procedures preauthorized up to a designated number or time frame are separately paid.

Payment for the **physician's professional services** associated with hospital-based procedures is usually based on the insurer's allowable rate schedule amount. The physician may separately bill **one Evaluation & Management (E & M) service** for a history/physical exam to determine the appropriateness of the **first day's procedure**.

Medicare. The Medicare Hospital Outpatient Prospective Payment System (HOPPS) assigns Ambulatory Payment Classification (APC) **0112** (Apheresis, Photopheresis and Plasmapheresis) to outpatient photopheresis claims coded with CPT 36522:



The **physician's professional services** are paid by submitting a claim (CMS-1500) to the local Medicare Carrier:



*Adjusted to reflect geographic wage variations using the hospital wage index; applied to the labor portion. If a different procedure is also performed on the same day, the APC 0112 for EPC is *not* discounted.

Focus on Extracorporeal Photopheresis – continued

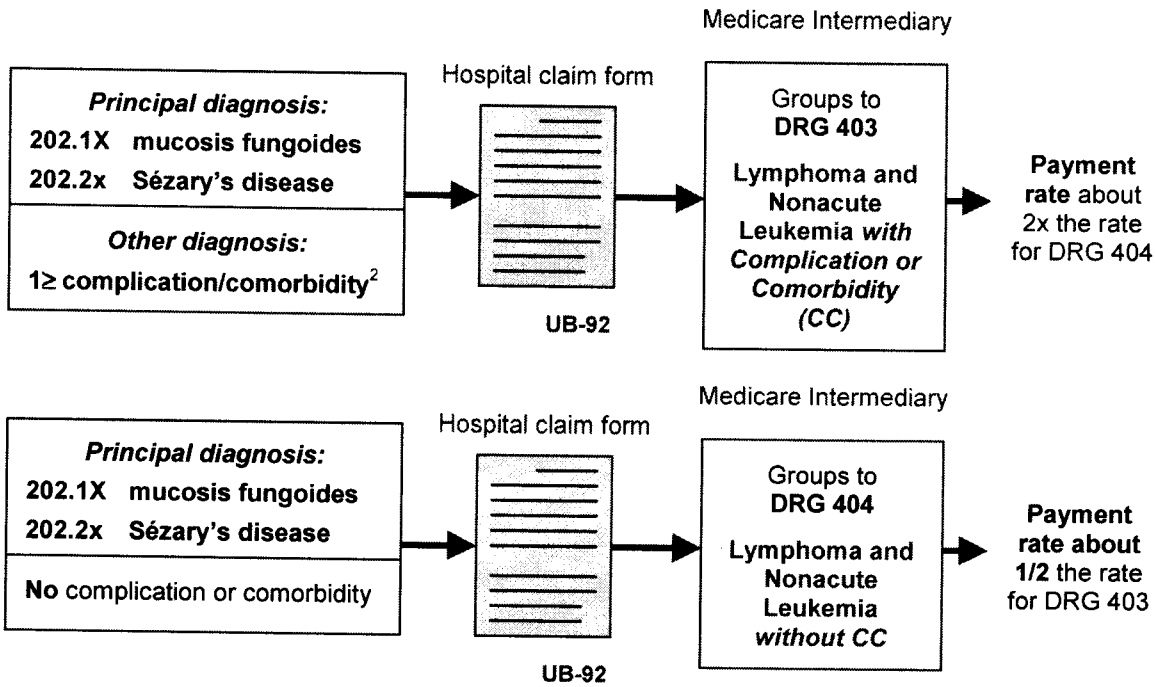
Payment: Hospital Inpatient

While most patients are treated with ECP on an outpatient basis, some may have already been hospitalized to acutely manage their illness. In selected instances, some physicians prefer to hospitalize the patient for his or her ECP therapy.

In the event that this procedure is provided in the inpatient setting, below are payment policies which most commonly apply.

Commercial insurers. The costs of ECP may be subsumed under a flat **per diem** payment rate negotiated between the hospital and the insurer; there is no separate payment for ECP in this circumstance. Less frequently, ECP may be subsumed under a fixed, prospectively determined payment rate for the entire hospital stay, or paid on the basis of a negotiated percentage of charges.

Medicare. Unlike Medicare outpatients, for whom payment is driven by the CPT 36522 procedure code, the two major Diagnosis-Related Groups (DRGs) which apply for inpatients treated for CTCL are driven by **ICD-9-CM diagnosis codes**:



Payment: Physician Office or Physician-Directed Clinic

Please refer to the guide section titled **"Expanded Medicare Payment for Office-Based Plasma Exchange, Immunoadsorption, LDL Apheresis and Photopheresis"** on page 10.

Focus on Extracorporeal Immunoadsorption (*PROSORBA*®)

Diagnosis Coding

The extracorporeal protein A immunoadsorption column (*PROSORBA* Column) procedure is indicated by the FDA for:

1. Therapeutic removal of IgG and IgG-containing circulating immune complexes from plasma in patients with **idiopathic thrombocytopenic purpura (ITP)** having platelet counts <100,000/mm^3.

Primary thrombocytopenias	**287.3**

2. Therapeutic reduction of signs and symptoms of moderate to severe **rheumatoid arthritis (RA)** in adult patients with long standing disease who have failed or are intolerant to disease modifying anti-rheumatic drugs (DMARDs).

Rheumatoid arthritis	**714.0**
Felty's syndrome	**714.1**
Other rheumatoid arthritis with visceral or systemic involvement	**714.2**
Juvenile chronic polyarthritis	**714.3**

The diagnosis code must be entered on all applicable claim forms.

Procedure Coding:

CPT 36515	Physicians – CMS-1500 Hospitals (Outpatient) – UB-92
ICD-9-CM 99.76	Hospitals (Inpatient) – UB-92

Coverage

According to Fresenius Hemocare, the *PROSORBA* Column is covered by Medicare, Medicaid programs and over 90% of private insurers.

Coverage policies may differ on specific criteria. For example, Medicare requires a platelet count that is "persistently at or below 25,000/mm^3," while the formal indication stipulates a platelet count <100,000/mm^3. As concerns RA, Medicare requires prior failure on at least 3 DMARDs, and does not consider intolerance to be akin to failure.

Medicare Coverage Policy for Protein A Columns (CPT 36515)*

ITP. Medicare will cover when used for the treatment of chronic refractory ITP, defined as having these criteria: (1) prior treatment failure with corticosteroids and splenectomy, (2) duration of illness >6 months, (3) no concurrent illness/disease explaining thrombocytopenia, and (4) platelet counts persistently at or below *25,000*/mm^3.

Rheumatoid arthritis (RA). Medicare will cover under the following conditions:

1. Patient has severe RA; disease is active, having >5 swollen joints, >20 tender joints, and morning stiffness >60 minutes.
2. Patient has failed an adequate course of a minimum of 3 disease modifying anti-rheumatic drugs (DMARDs). Failure does not include intolerance.

*Coverage Issues Manual §35-90

Focus on Extracorporeal Immunoadsorption (*PROSORBA*) – continued

Payment: Hospital Outpatient

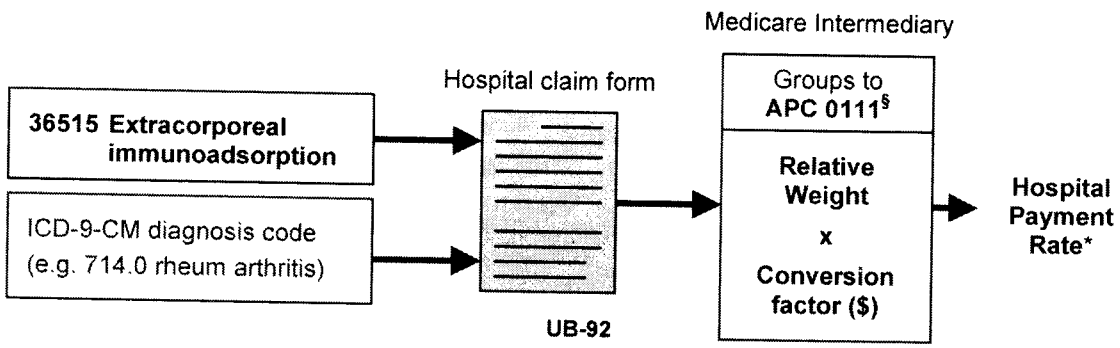
Commercial insurers. Payment for the technical component of a *PROSORBA* procedure is most commonly based on a **fixed percentage of the hospital's submitted charge** or the insurer's **fee schedule amount**. Periodically there may be a **negotiation** between the institution and the insurer to arrive at a mutually acceptable payment rate.

Payment for the **physician's professional services** is generally based on allowable amount listed in the insurer's rate schedule, which in turn is often tied to physician work RVUs (1.74 RVUs in 2005).

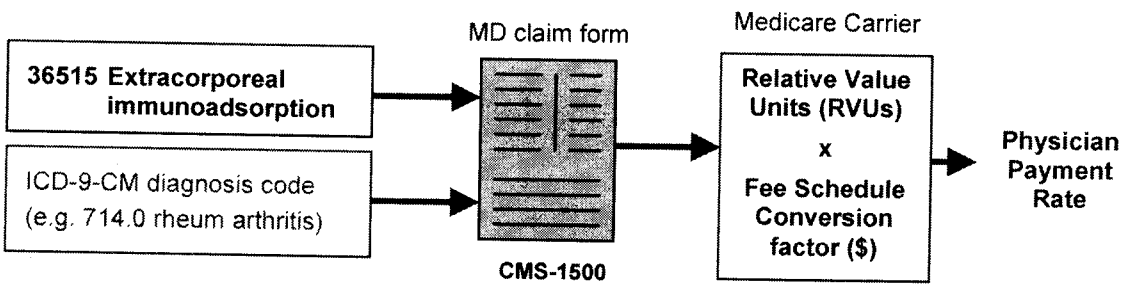
Medicare. The Medicare Hospital Outpatient Prospective Payment System (HOPPS) assigns Ambulatory Payment Classification (APC) **0111** (Apheresis, Photopheresis and Plasmapheresis) to outpatient *PROSORBA* procedure claims coded with CPT 36515:

NOTE: As a result of inaccurate coding instructions and consequent coding errors by hospitals, Medicare has changed the APC assignment for CPT 36515 from **APC 0112** (average payment rate ~$2,100) to **APC 0111** (average payment rate ~$725) for calendar year 2005.

The *Prosorba* manufacturer, providers and ASFA are working with CMS to restore the assignment to APC 0112. Check with your local Medicare Intermediary for CPT 36515 payment status.



The **physician's professional services** are paid by submitting a claim (CMS-1500) to the local Medicare Carrier:



*Adjusted to reflect geographic wage variations using the hospital wage index; applied to the labor portion. If a different procedure is also performed on the same day, the APC 0111 for the *PROSORBA* procedure is *not* discounted.

§Prior to 2005, this procedure was assigned to APC 0112; efforts are in progress to return it to APC 0112.

Focus on Extracorporeal Immunoadsorption (*PROSORBA*) – continued

Payment: Hospital Inpatient

While patients with refractory RA are ordinarily treated with *PROSORBA* Column therapy on an outpatient basis, some patients treated with *PROSORBA* for their ITP may be hospitalized to acutely manage this condition or an underlying illness.

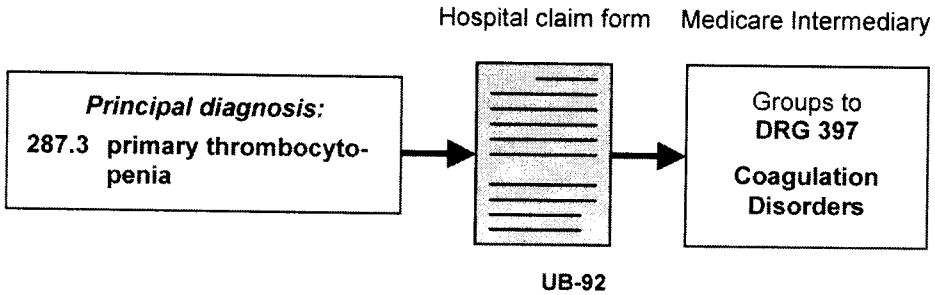
In circumstances where this procedure is provided in the inpatient setting, below are payment policies which most commonly apply.

Commercial insurers. The costs of a *PROSORBA* procedure may be subsumed under a flat **per diem** payment rate negotiated between the hospital and the insurer; there is no separate payment for a *PROSORBA* procedure in this circumstance. Less frequently, the procedure may be subsumed under a fixed, prospectively determined payment rate for the entire hospital stay, or paid on the basis of a negotiated percentage of charges.

Medicare. Unlike Medicare outpatients, for whom payment is driven by the CPT 36515 procedure code, Diagnosis-Related Groups (DRGs) which apply for inpatients treated with the *PROSORBA* Column are driven by **ICD-9-CM diagnosis codes**.

A given patient may be admitted for a variety of reasons, coinciding with a number of principal diagnosis possibilities and thus grouping to a number of possible DRGs.

If the patient happened to be admitted as the direct result of bleeding activity or signs or symptoms related to his or her thrombocytopenic state, ITP may be the principal diagnosis coded on the claim. The DRG would be assigned as follows:



Payment: Physician Office or Physician-Directed Clinic

Please refer to the guide section titled **"Expanded Medicare Payment for Office-Based Plasma Exchange, Immunoadsorption, LDL Apheresis and Photopheresis"** on page 10.

Focus on Selective Adsorption/Filtration (LDL Apheresis)

Diagnosis Coding

At present, two FDA-cleared LDL apheresis technologies[1] represent the only procedures which can be coded to CPT 36516. Other investigational procedures which selectively adsorb or filter out undesirable proteins or other plasma elements may also fall under CPT 36516 if they are licensed in the future for clinical use.

LDL apheresis is indicated for use in a narrowly defined patient population with **familial hypercholesterolemia (FH)** which requires chronic lowering of the plasma LDL cholesterol (LDL-C) level.

Diagnosis	*ICD-9-CM*
Pure hypercholesterolemia	**272.0**
Mixed hyperlipidemia*	**272.2**

*Not all insurers may cover claims coded with 272.2

Procedure coding:

CPT 36516*	Physicians – CMS-1500 Hospitals (Outpatient) – UB-92

* **S2120** is used by many Blue Cross and Blue Shield plans

Coverage

Medicare and most commercial insurers have defined coverage policies modeled closely on the FDA indications for the two licensed technologies. LDL apheresis is generally covered for patients who have completed, at minimum, a 6-month trial of an American Heart Association Step II diet (or equivalent) and maximum tolerated combination drug therapy designed to reduce LDL-C, and at their baseline examination meet the following additional criteria:

1. Heterozygous FH with LDL cholesterol (LDL-C) ≥ 300 mg/dl;
2. Heterozygous FH with LDL-C ≥ 200 mg/dl and documented coronary heart disease (CHD); and
3. Homozygous FH with LDL-C > 500 mg/dl.

Some coverage policies specify types of lipid-lowering drugs that must have been evaluated.

Definition of Coronary Heart Disease (CHD) for LDL Apheresis Coverage

CHD is defined as having one or more of the following:

- A prior documented myocardial infarction (MI);
- A prior coronary artery bypass graft (CABG) surgery;
- A prior percutaneous transluminal coronary angioplasty (PTCA) with or without atherectomy or coronary artery stent placement; and
- Angina pectoris with a positive thallium or other heart scanning stress test.

[1] *Liposorber*® (Kaneka America) and *HELP System* (B. Braun Medical).

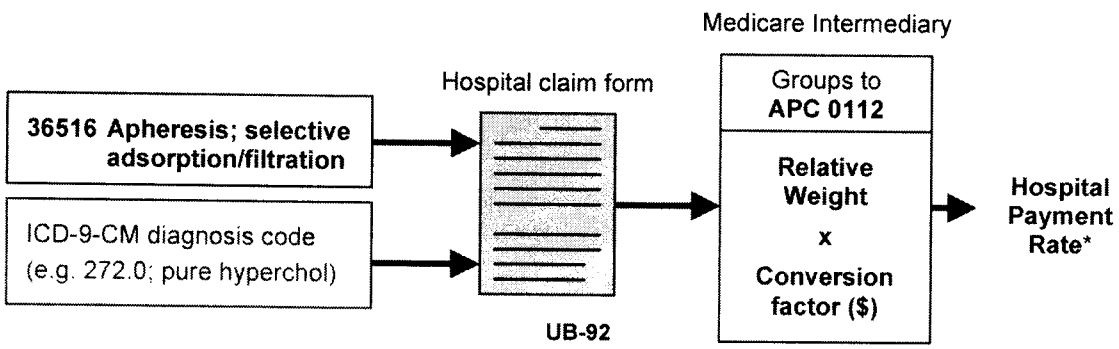
Focus on Selective Adsorption/Filtration (LDL Apheresis) - continued

Payment: Hospital Outpatient

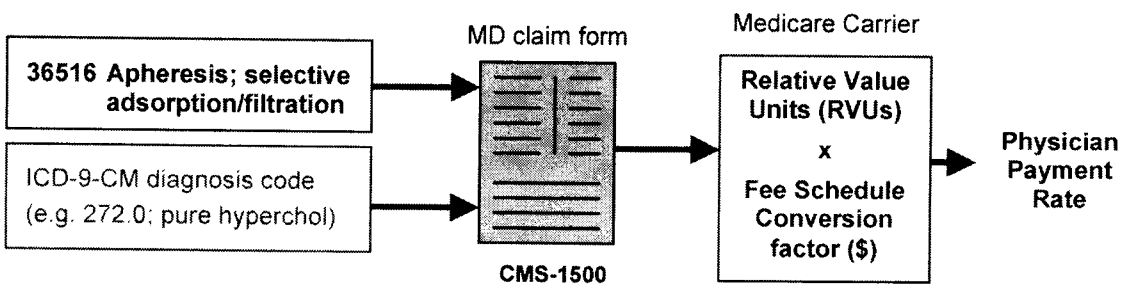
Commercial insurers. Payment for the technical component of an LDL apheresis procedure is most commonly based on a **fixed percentage of the hospital's submitted charge** or the insurer's **fee schedule amount**. There is sometimes a **negotiation** between the institution and the insurer to arrive at a mutually acceptable payment rate.

Payment for the **physician's professional services** associated with hospital-based LDL apheresis procedures is usually based on the allowable amount listed in the insurer's rate schedule, which in turn is often tied to physician work RVUs (1.22 RVUs in 2005).

Medicare. The Medicare Hospital Outpatient Prospective Payment System (HOPPS) assigns Ambulatory Payment Classification (APC) **0112** (Apheresis, Photopheresis and Plasmapheresis) to outpatient LDL apheresis claims coded with CPT 36516:



The **physician's professional services** are paid by submitting a claim (CMS-1500) to the local Medicare Carrier:



Payment: Physician-Directed Clinic

Please refer to the guide section titled **"Expanded Medicare Payment for Office-Based Plasma Exchange, Immunoadsorption, LDL Apheresis and Photopheresis"** on page 10.

Payment: Hospital Inpatient

LDL apheresis is not provided on a hospital inpatient basis. Should such an instance occur, payment policies will conform to the same principles described for CPT 36514, CPT 36515 and CPT 36522.

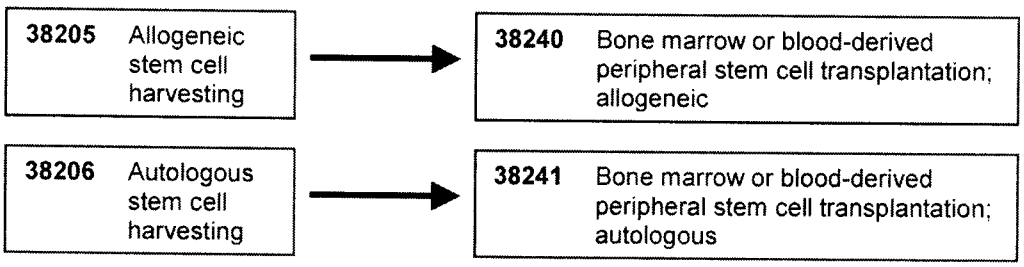
*Adjusted to reflect geographic wage variations using the hospital wage index; applied to the labor portion. If a different procedure is also performed on the same day, the APC 0112 for the LDL apheresis procedure is *not* discounted.

Focus on Blood-Derived Stem Cell Harvesting

In 2003, two new CPT procedure codes were created to identify and bill apheresis-based collection of peripheral blood stem cells from autologous and allogeneic donors:

38205	Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; allogeneic
38206	Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; autologous

Allogeneic (**CPT 38205**) or autologous (**CPT 38206**) stem cells acquired from one or more donor procedures are later transplanted into the intended recipient in a separately coded procedure on a separate claim form (and may be performed by a different entity):



Diagnosis Coding and Coverage

In the same vein as diagnosis coding for therapeutic apheresis procedures, insurers review claims for stem cell harvesting to confirm the presence of a diagnosis for which both the harvesting and transplantation procedures are "reasonable and necessary."

A claim for the outpatient stem cell harvesting procedure should identify the diagnosis (e.g. the leukemia, lymphoma, aplastic anemia or other ICD-9-CM coded condition) **for which the transplantation procedure is intended**. This applies also for the healthy matched allogeneic donor whose stem cells are being harvested for transplantation into a specified recipient; the ICD-9-CM diagnosis code corresponding to the recipient's condition requiring the transplant should be entered on the claim for the donor stem cell harvesting procedure.

Based on Medicare's National Coverage Determination for stem cell transplantation,* local Medicare Fiscal Intermediaries screen claims to ascertain that a stem cell harvesting procedure was performed for a covered condition. An abridged example follows:

* Medicare National Coverage Determination, Section 110.8.1 (Rev. 13, 05-28-04); CIM 35-30.1.

Focus on Blood-Derived Stem Cell Harvesting – continued

Example of a local Medicare Intermediary's coverage policy applicable to stem cell harvesting and transplantation:

Allogeneic Stem Cell Transplantation **(CPT 38205, 38240)**

The following uses are **covered** under Medicare when reasonable and necessary:

- Leukemia and leukemia in remission: ICD-9-CM codes **204.0** through **208.9**
- Aplastic anemia, ICD-9-CM codes **284.0** through **284.9**
- Severe combined immunodeficiency disease (SCID), ICD-9-CM code **279.2**
- Wiskott-Aldrich syndrome, ICD-9-CM code **279.12**

Allogeneic SCT is not covered for multiple myeloma, ICD-9-CM codes **203.00** and **203.01**.

Autologous Stem Cell Transplantation **(CPT 38206, 38241)**

The following uses are **covered** under Medicare when reasonable and necessary:

- Acute leukemia in remission with a high probability of relapse and no human leucocyte antigens (HLA)-matched: ICD-9-CM codes **204.01**, 205.01, 206.01 **and** 208.01
- Resistant non-Hodgkin's or those presenting with poor prognostic features following an initial response: ICD-9-CM codes **200.00 – 200.08, 200.10 – 200.18, 200.20 – 200.28, 200.80 – 200.88, 202.00 – 202.08, 202.80 – 202.88 and 202.90 – 202.98**
- Recurrent or refractory neuroblastoma
- Advanced Hodgkin's disease (**201.00 – 201.98**) patients who have failed conventional therapy and have no HLA-matched donor
- Durie-Salmon Stage II or III patients that fit specified requirements; includes multiple myeloma (**203.00 and 238.6**) and primary amyloidosis (**277.3**)

Autologous stem cell transplantation is noncovered for acute leukemia not in remission (5 codes), chronic granulocytic leukemia (2 codes), solid tumors, etc.

Payment: Hospital Outpatient

Commercial insurers. Payment for the large majority of stem cell harvesting procedures falls under a **negotiated global case rate** for all transplantation-related services, A UB-92 claim form is still completed and submitted, but payment will be a fixed amount agreed to by the hospital and insurer.

Otherwise, payment for the technical component of a stem cell harvesting procedure is most commonly based either on a **fixed percentage of the hospital's submitted charge** or the insurer's **rate schedule** for CPT 38205 and 38206. If multiple harvesting procedures are required, they would be individually paid.

When not subsumed under a global payment rate agreement, payment for the **physician's professional services** associated with hospital-based stem cell harvesting is usually based on the insurer's allowable rate schedule amount, which in turn is generally tied to the physician work RVUs (1.5 RVUs in 2005) for the procedure.

Medicare. APC **0111** (Blood Product Exchange) applies for outpatient claims coded with **CPT 38205** or **38206**. Multiple procedures performed on different days are separately payable. This applies also to billing for **physician services**, payable on the basis of **2.24 RVUs** (1.5 MD work; 0.67 practice expense; 0.08 malpractice cost). These same physician service RVUs apply in the event the procedure is performed on an inpatient basis.

Focus on Intravascular Access Device (IVAD) Maintenance

Defining and Documenting Costs of Catheter Declotting

Declotting the implanted vascular access device (IVAD) used for venous access in some therapeutic apheresis patients engenders significant nurse technician labor, thrombolytic drug and supply costs.

It is important both to fully account for these costs and have robust standard procedures in place to assure that entries or charge slips are generated for your billing department to include in the insurance claim.

Coding Opportunities

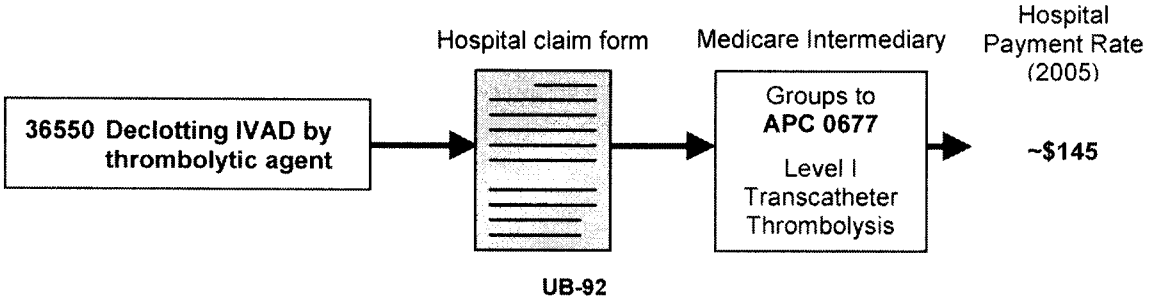
The following codes should be identified in the claim as appropriate:

CPT or HCPCS-II	*Procedure or item description**
36550	Declotting by thrombolytic agent of implanted vascular access device or catheter
J2997	Injection, alteplase recombinant, 1 mg
J3364	Injection, urokinase, 5000 IU vial

*Bill multiple units when multiple units are used (e.g. bill 3 units of J2997 for 3 mg alteplase).

Coding for Medicare Payment in the Hospital Outpatient Setting

For **Medicare beneficiaries** whose catheter occlusions are treated in the **hospital outpatient department**, the CPT procedure code **36550** groups to an Ambulatory Payment Classification (APC):



Medicare has assigned this particular APC has a "T" status indicator, which means that, if more than one APC with this same "T" status indicator is assigned on the same date of service, the one with the highest payment rate will be paid on a 100% basis, while all other procedures with the "T" designation will be paid at 50% of the normal payment rate.

All outpatient therapeutic apheresis procedures group to APCs *without* "T" status indicator, and are never discounted. In the likely circumstance that the declotting procedure is the only other CPT-coded service that groups to an APC, it will also be fully paid.

Appendix 1

USEFUL DOCUMENTATION TO INCLUDE IN A "STATEMENT OF MEDICAL NECESSITY" FOR INSURANCE PREAUTHORIZATION

[Date] [Medical Director name] [Insurance entity and address]

Patient name: **Name in bold**
Insurance plan number: **Number in bold**

- Document **patient age**, **diagnostic work-up**, and related **clinical history**. As appropriate, attach and reference test findings, disease scoring worksheets, etc. to more fully portray the patient's clinical course and status.

- If applicable, include **detailed review of conventional therapy and documentation of the disappointing nature of the patient's response**.

- Briefly overview **how the procedure works**, and **its advantages in relation to other treatment alternatives**.

- Describe your treatment plan: initial frequency and continuing frequency and length of therapy scenarios based on alternative response patterns.

- Educate the insurance plan's Medical and/or Associate Medical Director about the clinical rationale for therapeutic apheresis in this particular patient:

  → **Cite *and enclose* copies of authoritative studies or reviews** which document the therapeutic benefit of the procedure in similar patients. *Cite literature which provides supportive evidence and conclusions.*

  → **Cite formal technology assessments which support the medical necessity of therapeutic apheresis as primary, adjunctive or salvage therapy for your patient**, as applicable.

  → **Ask for preauthorization of a specified number of treatments** likely to be required, again accompanied by either a major review or several citations in the literature which corroborate the use of a series of treatments.

  Insurers want and need a proposed treatment algorithm which (1) is reasonably consistent with the body of evidence in the published literature, and (2) allows a case manager to monitor progress and assure that futile or minimally effective therapy is *not* provided and billed.

- **Point out the urgency of a prompt response**, to enable your patient to begin receiving treatment as soon as possible. Note (as appropriate) that **earlier initiation of therapy generally yields better outcomes**, and again cite one or more supportive references; if available, enclose them in your letter.

- Offer to provide any **additional information** that might be needed concerning this patient, and include your direct telephone number. Use **a courteous and professional tone** throughout the letter.

Appendix 2

Diseases and ICD-9-CM Diagnosis Codes Designated by ASFA/AABB as Category I, II and III Applications of Therapeutic Apheresis[1]

Category I: Diseases for which therapeutic apheresis is standard and acceptable, either as a primary therapy or a valuable first-line adjunct therapy

Category II: Diseases for which therapeutic apheresis is generally accepted but considered to be supportive or adjunctive to other, more definitive treatments, rather than a first-line therapy

Category III: Diseases in which there is a suggestion of benefit for which existing evidence is insufficient, either to establish the efficacy of therapeutic apheresis or to clarify its risk/benefit ratio.

Disease	ICD-9-CM dx code[2]	Procedure	Indication category
Renal and metabolic diseases			
Anti-glomerular basement membrane antibody disease	583.89	Plasma exchange	I
Rapidly progressive glomerulonephritis	583.4[3]	Plasma exchange	II
Hemolytic uremic syndrome	283.11	Plasma exchange	III
Renal transplantation			
Presensitization	V42.0	Plasma exchange	III
Recurrent focal glomerulosclerosis	42.0/582.1	Plasma exchange	III
Heart transplant rejection	996.83	Plasma exchange	III
		Photopheresis	III
Acute hepatic failure	MC	Plasma exchange	III
Familial hypercholesterolemia	272.0[4] 272.2[4]	Selective adsorption	I
		Plasma exchange	II
Overdose poisoning	MC	Plasma exchange	III
Phytanic acid storage disease	ND	Plasma exchange	I
Autoimmune and rheumatic diseases			
Cryoglobulinemia	273.2	Plasma exchange	II
Idiopathic thrombocytopenic purpura	287.3	Immunoadsorption	II
Raynaud's phenomenon	443.0	Plasma exchange	III
Vasculitis	MC	Plasma exchange	III
Autoimmune hemolytic anemia	283.0	Plasma exchange	III
Rheumatoid arthritis	714.0	Immunoadsorption	II
		Lymphoplasma-pheresis	II
Scleroderma/progressive systemic sclerosis	710.1	Plasma exchange	III
Systemic lupus erythematosus	710.0	Plasma exchange	III

[1]Sources: *J Clin Apheresis* 2000; 15:1-5. *Transfusion* 2003; 43:821-22.

[2] It is the sole responsibility of the provider to independently verify the accuracy of all codes submitted on insurance claims; ND = not determined for inclusion in this guide; MC = various or multiple codes required.

[3] If also specified as "acute" glomerulonephritis, use 580.4; if also specified as "chronic," use 582.4.

[4] 272.0 = pure hypercholesterolemia; 272.2 = mixed hyperlipidemia.

Disease	ICD-9-CM dx code[1]	Procedure	Indication category
Hematological diseases			
ABO incompatible marrow transplant	ND	Red cell removal (marrow)	I
		Plasma exchange (recipient)	II
Erythrocytosis/polycythemia vera	MC	Phlebotomy	I
		Erythrocytapheresis	II
Leukocytosis and thrombocytosis	MC	Cytapheresis	I
Thrombotic thrombocytopenic purpura	446.6	Plasma exchange	I
Post-transfusion purpura	287.4	Plasma exchange	I
Sickle cell diseases	MC	Red cell exchange	I
Myeloma/paraproteins/hyperviscosity	MC	Plasma exchange	II
Myeloma/acute renal failure	MC	Plasma exchange	II
Coagulation factor inhibitors	286.5	Plasma exchange	II
Aplastic anemia/pure red cell aplasia	MC	Plasma exchange	III
Cutaneous T-cell lymphoma	page 16	Photopheresis	I
		Leukapheresis	III
Hemolytic disease of the newborn	773.0	Plasma exchange	III
Platelet alloimmunization and refractoriness	ND	Plasma exchange	III
		Immunoadsorption	III
Malaria/babesiosis	MC	Red cell exchange	III
Neurological disorders			
Chronic inflamm demyelinating polyradiculoneuropathy	356.9	Plasma exchange	I
Acute inflamm demyelinating polyradiculoneuropathy	357.0	Plasma exchange	I
Lambert-Eaton myasthenic syndrome	358.1	Plasma exchange	II
Multiple sclerosis			
Relapsing	340	Plasma exchange	III
Progressive	340	Plasma exchange	III
Myasthenia gravis	358.0	Plasma exchange	I
Acute CNS inflammatory demyelinating disease	341.9	Plasma exchange	II
Paraneoplastic neurologic syndromes	MC	Plasma exchange	III
		Immunoadsorption	III
Demyelinating polyneuropathy with IgG/IgA	ND	Plasma exchange	I
		Immunoadsorption	III
Sydenham's chorea	392.9	Plasma exchange	II
Polyneuropathy with IgM (± Waldenstrom's)	MC	Plasma exchange	II
		Immunoadsorption	III

[1]It is the sole responsibility of the provider to independently verify the accuracy of all codes submitted on insurance claims; ND = not determined for inclusion in this guide; MC = various or multiple codes required.

Disease	ICD-9-CM dx code[1]	Procedure	Indication category
Cryoglobulinemia with polyneuropathy	MC	Plasma exchange	II
Multiple myeloma with polyneuropathy	MC	Plasma exchange	III
POEMS syndrome	ND	Plasma exchange	III
Polymyositis or dermatomyositis	MC	Plasma exchange	III
Inclusion-body myositis	ND	Plasma exchange	III
Rasmussen's encephalitis	ND	Plasma exchange	III
Stiff-Man syndrome	333.91	Plasma exchange	III
PANDAS	ND	Plasma exchange	II

[1]It is the sole responsibility of the provider to independently verify the accuracy of all codes submitted on insurance claims; ND = not determined for inclusion in this guide; MC = various or multiple codes required.

Appendix 3

2005 HCPCS Codes for Billing Albumin, FFP and Red Blood Cells

HCPCS-II Code	Albumin Products
P9041	Infusion, albumin (human), 5%, 50 ml
P9043	Infusion, plasma protein fraction (human), 5%, 50 ml
P9045	Infusion, albumin (human), 5%, 250 ml
P9046	Infusion, albumin (human), 25%, 20 ml
P9047	Infusion, albumin (human), 25%, 50 ml
P9048	Infusion, plasma protein fraction (human), 5%, 250 ml

HCPCS-II Code	FFP and Red Blood Cell Products
P9010	Blood (whole), for transfusion, per unit
P9011	Blood (split unit), specify amount
P9012	Cryoprecipitate, each unit
P9016	Red blood cells, leukocytes reduced, each unit
P9017	Fresh frozen plasma (single donor), frozen within 8 hours of collection, each unit
P9021	Red blood cells, each unit
P9022	Red blood cells, washed, each unit
P9038	Red blood cells, irradiated, each unit
P9039	Red blood cells, deglycerolized, each unit
P9040	Red blood cells, leukocytes reduced, irradiated, each unit
P9044	Plasma, cryoprecipitate reduced, each unit
P9051	Whole blood or red blood cells, leukoreduced, CMV-negative, each unit
P9054	Blood, leukoreduced, frozen, deglycerolized, washed, each unit
P9056	Whole blood, leukoreduced, irradiated, each unit
P9057	Red blood cells, frozen/deglycerolized/washed, leukocyte-reduced, irradiated, each unit
P9058	Red blood cells, leukocyte-reduced, CMV negative, irradiated, each unit
P9059	Fresh frozen plasma between 8-24 hours of collection, each unit
P9060	Fresh frozen plasma, donor retested, each unit

Appendix 4

Glossary of Selected Insurance Terms

Allowable amount. The maximum amount an insurer will "allow" the provider for a service or supply, representing the total of the insurer's payment and the patient's balance payment.

Ambulatory Payment Classification (APC). A four-digit designation to which related outpatient hospital procedures which use similar resources are assigned; each APC is assigned a payment rate.

Beneficiary. A person eligible to receive benefits under an insurance policy.

Carrier. An insurance company that "carries" insurance; the preferable term is "insurer." A Medicare Carrier contracts with Medicare to process claims from physicians and freestanding non-hospital facilities paid under Medicare's Part B benefits.

Claim. The demand for benefits as provided by an insurance policy.

CMS. The Centers for Medicare and Medicaid Services; formerly the Health Care Financing Administration (HCFA). The federal government agency that administers Medicare, Medicaid and Child Health Insurance Programs.

CMS-1500 claim form. The standard claim form required by Medicare and other health insurers for billing physician services.

Coinsurance. The percentage of the cost of care for which the patient is responsible; this often applies after a specific deductible is met.

Current Procedural Terminology (CPT). A listing of descriptive terms and codes for reporting medical services and procedures performed by physicians, which is maintained by the American Medical Association.

Deductible. The initial amount the patient is responsible for paying in a calendar year for particular covered services before insurance coverage begins.

Diagnosis-Related Group (DRG). A method used by Medicare and some other insurers to group inpatient hospital stays by principal and other diagnoses, procedures, patient age, patient gender and discharge status. These DRGs are assigned predetermined fixed payments per episode of care, independent of resource usage.

Explanation of benefits (EOB). Documentation which accompanies payment of a claim, explaining (1) what was covered and not covered and why, (2) the payment rates or allowable amounts for billed services and products, (3) the amounts paid by the insurer, and (4) the amounts, if any, which are the patient's responsibility.

Fiscal Intermediary. An organization that contracts with Medicare to process claims from hospitals and other providers which are paid under Medicare's Part A benefits.

Glossary of Selected Insurance Terms – continued

Global period. Services which follow and are directly related to the initial procedure over a defined "global period" are considered part of the initial procedure and are subsumed under its payment rate (i.e. not separately payable).

Global payment rate. A single payment rate for both hospital and physician services.

Hospital Outpatient Prospective Payment System. The Medicare program's system for classification and payment of outpatient services.

ICD-9-CM. An acronym for International Classification of Diseases, 9th Revision, Clinical Modification, this is listing of diagnostic (Vol. 1 and 2) and procedural (Vol. 3) codes.

Local Medical Review Policy (LMRP). A coverage policy established by a local Medicare Carrier or Fiscal Intermediary, which addresses a medical service or procedure.

Medically necessary services. A covered service that is required for the diagnosis or treatment of an illness or injury, or preserve the health status of an eligible person in accordance with local standards of medical practice.

Medicare Part A and Part B. Hospital and medical insurance, respectively, under Medicare.

Modifier. Appended to a CPT code to further specify the nature of the service (e.g. the modifier "-TC" indicates only the technical component of the service).

Preauthorization (also precertification and prior authorization). A method to monitor and control utilization of a medical service by requiring a determination of whether it is both medical necessary and covered under the insurance plan prior to that service.

Providers. Institutions and individuals licensed to provide health care services (e.g. hospitals, physicians, pharmacists).

Relative value unit (RVU). A standard for measuring the value of a medical service provided by physicians relative to other medical services provided by physicians. Each service RVU has three components: physician work, overhead (reflecting all categories of practice expenses) and malpractice expense.

Revenue codes. A 3-digit coding system used to categorize hospital services for billing purposes.

UB-92 claim form. The standard claim form required by Medicare and other insurers for billing hospital services.

Usual, Customary and Reasonable (UCR). A physician charge deemed reasonable for a service, which does not exceed his or her usual charges or the amount customarily charged by other physicians in the area for the service. Often defined as a specific percentile of all charges for services in the community.

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September 8, 2005

Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; CMS-1501-P; Device-Dependant APCs.

Dear Doctor McClellan:

I am writing on behalf of the Council of The American Otological Society and wish to convey our concerns regarding the proposed payment rate for cochlear implant devices/systems (APC 0259). The American Otological Society represents over 300 senior specialists who provide ear and hearing care on a daily basis. For properly screened and counseled patients who are unable to enjoy the benefit of sound with hearing aids, the availability of the cochlear implant has been a lifeline.

If the CMS APC 0259 proposed reductions were adopted, payment levels for cochlear implantation would decline by 14%. Such a decline in Medicare payment, which is already well below actual cost for many hospitals, will substantially disrupt cochlear implant services to Medicare beneficiaries. As you are aware, cochlear implant reimbursement levels have experienced increases in CMS payment levels in recent years. These increments have helped to offset the losses experienced by implant programs by bringing reimbursement closer to actual costs. However, if enacted, APC 0259 would lower reimbursement to an untenable level. Please note that implant costs have increased for providers every single year since 2000.

Ready access is required for cochlear implantation to be effective in seniors. Follow-up care, mapping the device's electronics and maintaining a well tuned, functional device is critical to ensuring optimal results. Typically, 4 to 8 visits are required in the first year after surgery and though this number lessens in subsequent years, that first year is critical to outcomes. If reimbursement cutbacks were to reduce access to services, seniors would be forced to travel longer distances for after-surgery care and less likely to be achieve optimal outcomes.

Access to cochlear implant services has been observed in several studies to carry measurable benefit to health-related quality of life. More, these benefits have been observed to yield cost-effectiveness ratings that place cochlear implantation of seniors in a highly favorable position in

its value relative to other covered interventions. Cochlear implantation increases the independence of Medicare beneficiaries through self-sufficiency and maintaining social networks.

The American Otological Society requests that CMS substitute accurate external device cost data in recalculating the relative weight of APC 0259. We understand that if this were done, the APC payment would approximate $27,200 for the combined device- and hospital facility-cost of cochlear implantation. This would place reimbursement levels closer to estimated costs at many institutions which exceed $32,000.

Please let me know if I can provide further information.

Sincerely,

John K. Niparko MD (Johns Hopkins University)
President
The American Otological Society

Registered to attend the Town Hall Meeting September 12, 2005

7500 Security Blvd., C4-05-17

Baltimore, MD 21244-1850

2 PM to 4 PM (extended past 4:00 PM)

Presenter: Patricia Jost Golden, RN, Hemapheresis Practitioner (ASCP)

Immediate Past President American Society for Apheresis (ASFA)

Chair of ASFA Public Affairs Committee

Seated on:

American Society for Hematology Committee on Practice member

American Society for Clinical Pathology Board of Registry Board of Governors

Hemapheresis Practitioner Certification Exam Committee

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Disclosure of Financial Relationships:

Vice President and Co-Director PhereSys Therapeutics, Midwest Region

CPT Codes Involved:

Proposed HOPPS Rule 2006:

CPT/ HCPCS	Description	2005 APC	2006 APC	2005 Pmt Rate	2006 Proposed Pmt Rate	Payment Rate Difference
36511	Apheresis WBC	0111	0111	$725.16	$732.34	$7.18
36512	Apheresis RBC	0111	0111	$725.16	$732.34	$7.18
36513	Apheresis platelets	0111	0111	$725.16	$732.34	$7.18
36514	Apheresis plasma	0111	0111	$725.16	$732.34	$7.18
36515	Apheresis, adsorp/reinfuse	111	0112	$725.16	$1,583.07	$857.91
	(36515 was inadvertently placed in APC 0111 in 2005. A petition was made at the APC advisory Committee meeting in February of 2005 to return CPT 36515 to APC 0112)					
36516	Apheresis, selective	0112	0112	$2,127.26	$1,583.07	-$544.19
36522	Photopheresis	0112	0112	$2,127.26	$1,583.07	-$544.19
38205	Harvest allogenic stem cells	111	0111	$725.16	$732.34	$7.18
38206	Harvest auto stem cells	0111	0111	$725.16	$732.34	$7.18

APC affected: 0112

ASFA, the premier American society devoted to apheresis medicine represents an eclectic group of healthcare professionals from diverse fields of medicine. Our membership includes physicians and allied health professionals from hematology, transfusion medicine, nephrology, neurology, rheumatology, cardiology and other fields which employ apheresis in medical practice. Our society, therefore, represents a broad range of fields whose common interest is apheresis.

The American Society for Apheresis (ASFA) appreciates this opportunity to present comments on the 2006 proposed Hospital Out Patient Prospective Payment System (HOPPS) Rule regarding Ambulatory Payment Classification 0112 and CPT codes 36515, 36516, and 36522. The proposed 2006 HOPPS reimbursement for APC 0112 is $1583.07, a 25% decrease in payment from the 2005 amount of $2, 127.26.

The APC 0112 currently includes three CPT codes: Code 36515 (Therapeutic Apheresis with Extracorporeal Immunoadsorption and Plasma Reinfusion) used to treat individuals with immune thrombocytopenic purpura (287.3) refractory to conventional therapy and advanced rheumatoid arthritis (714.0) unresponsive to at t least two conventional disease modifying anti-rheumatic drugs. Code 36516 (therapeutic Apheresis with Extracorporeal Selective Adsorption or Selective Filtration and Plasma Reinfusion) is used to treat patients with hypercholesterolemia (272.x) whose LDL levels are not controlled by maximum drug and diet therapy and are at high risk for adverse cardiac events. Code 36522 (Photopheresis, Extracorporeal) is used to treat individuals with cutaneous t-cell lymphoma of various types (202.1, 202.2). Photopheresis, Extracorporeal is being used increasingly to treat graft versus host disease in bone marrow transplant patients and to prevent solid organ transplant rejection. All three of these procedures require the use of sophisticated and costly equipment and supplies and take several hours of direct supervision by a clinical professional.

A short history of the CPT and APC codes that are related to apheresis will aid in understanding why the payment data may have been misinterpreted.

CPT code 36515 currently refers primarily to immunoadsorption using the Prosorba® column device, The CPT code 36515 is the successor code to CPT 36521, which was created in January 2000 when Prosorba® was approved for treatment of rheumatoid arthritis. Most other therapeutic apheresis treatments, such as plasma exchange, were coded during that time using CPT 36520. The code 36521 was assigned in the year 2000 to APC 0111 along with 36520. However, at that time it was established that the colloid exchange fluids for plasma exchange would be separately billed under their own APCs (e.g. APC 0963 for 5% human albumin) and the disposable Prosorba® column would be billed under its own APC 0976. Thus APC 0111 covered the procedure costs and other APCs covered the expensive supply costs.

On March 1st, 2001 the APC Advisory Committee agreed to a recommendation from the American Society of Hematology and ASFA that CPT 36521 be moved out of APC 0111 and into APC 0112 which, at that time, included only CPT 36522 (photopheresis). The specialized nature of procedures coded by 36521 (which by then included low density lipoprotein (LDL)-apheresis as well), and the cost of materials required to provide them rendered 36521 more similar to photopheresis than to plasma exchange. A further recommendation was that, at the same time, the separate APC for Prosorba® columns would be discontinued and thus the entire reimbursement for Prosorba® column apheresis treatments would be accounted for by the payment for APC 0112. This went into effect in 2002.

In November 2001 the Editorial Committee of the AMA, in an effort to improve granularity, agreed to publish new CPT codes for therapeutic apheresis in place of 36520 and 36521. Code 36520 was succeeded by new codes 36511-36514 which were to be used for therapeutic apheresis for white cells, red cells, platelets and plasma exchange respectively. Code 36521 was succeeded by two additional codes: 36515 which was to be used for immunoadsorption procedures such as Prosorba® column treatments and 36516 which was to be used for other

plasma adsorption or filtration treatments such as LDL-apheresis. These codes were valued by the RUC in 2002 and went into effect with CPT 2003. Unfortunately, a misprinted parenthetical in the 2003 and 2004 CPT manuals stated: "Code 36521 has been deleted. To report, use 36516", which thus incorrectly gave the impression that 36515 did not exist. This has been corrected for the 2005 CPT manual to read: "Code 36521 has been deleted. To report, use 36515, 36516." However it is apparent that for the years 2003 and 2004, physicians and hospitals were provided misleading information as to the proper successor code to 36521 for Prosorba® treatments.

In the 2006 Proposed HOPPS rule, which reflects the recent valuation of CPT codes 36515, 36516, and 36522, in the facility setting the value of APC 0112 is proposed as $1583.07. The acquisition cost to providers of the Prosorba® column alone is listed at $1,400.00. The additional equipment, supply, and staffing cost of providing the therapy is close to the value of APC 0111 ($732.34), bringing the total to approximately $2,132.34. Clearly the $1,583.07 value of APC 0111 will not cover the cost of the Prosorba® column procedure.

The same is true for the delivery of the procedures included in CPT code 36516, apheresis – selective, which at this time include LDL apheresis. The cost of the tubing needed for the equipment used is listed at approximately $2,271.00. The total expense in providing these therapies has been reported by ASFA members to be approximately $3, 300.00.

Code 36522, Photopheresis, Extracorporeal represents 85% of the single claims used to calculate the APC 0112 reimbursement rate. The direct costs per photopheresis procedure are reported to be $1980.00. Additional ancillary costs bring the total expense in providing photopheresis therapies to over $2425.00

We appreciate the process used to determine the proposed reimbursement rate that being the estimated median costs converted from hospital charges attributed to this APC. However, some hospitals obviously did not correctly submit charges that reflect the costs of the expensive equipment, supplies and ancillaries used for these procedures, perhaps due to the practice of

"charge compression". We suspect that if the rates were derived from adding the separate charges submitted for procedure supplies and for the procedure charge itself, the average charges would be significantly higher. We would ask CMS to consider evaluating the submitted claims in which separation of procedure and procedure supplies can be identified.

We would ask that CMS reexamine the calculation of median costs of the codes 36515, 36516, and 36522. It appears that an error has been made. Code 36522 represents 85% of the single claims used to calculate the APC 0112 rate. The median cost of all three procedures in APC 0112 is in excess of $2, 500.00, far in excess of the $1620 amount used in calculating the APC rate.

New applications of therapeutic apheresis are very close to becoming available for treatment of patients with dry age-related macular degeneration, and congestive heart failure. These new therapies have shown great promise in pivotal trial studies or have been already approved by the FDA for patient treatment. Unless the proposed payment rate for APC 0112 is corrected these therapies may not become available to the Medicare beneficiaries who need them the most. We know that this is not the goal of the HOPPS.

This proposed change will result in unacceptable financial losses to hospitals that provide these therapeutic apheresis procedures to Medicare beneficiaries. The result will be the inaccessibility of necessary apheresis therapy for patients who have no other treatment options after failing pharmaceutical remedies.

ASFA would ask that CMS:

1. Reexamine the calculation of the APC 0112
2. Consider basing the rate calculation on claims that have separation of apheresis supplies and apheresis procedure

3. Freeze the current reimbursement rate if CMS finds it impractical to review single claims for APC 0112

ASFA would offer to:

1. Prepare an education program for hospitals that provide apheresis procedures in their outpatient setting

2. Work with other stakeholder societies and CMS to prospectively collect data regarding actual costs involved in the hospital outpatient setting

3. Collaborate with other stakeholder societies and CMS on an advisory committee to review the data collection and interpretation related to therapeutic apheresis APC's 0111 and 0112

Our society is ready to work with CMS to resolve this and any other matters relevant to our field. On behalf of the members of the American Society for Apheresis I express my gratitude for this opportunity to express our comments on the proposed HOPPS rule.

Sincerely,

Patricia Jost Golden

Patricia J. Golden, RN, HP (ASCP)
Immediate Past President, American Society for Apheresis (ASFA)
Chair ASFA Public Affairs Committee

Submitter : **Dr. Costa Papastephanou** **Date: 09/15/2005**

Organization : **Ortec International, Inc.**

Category : **Device Industry**

Issue Areas/Comments

GENERAL

GENERAL

This comment is an addendum to our original comments submitted on August 22, 2005. In our previous letter, we addressed an error that we identified in the Hospital Outpatient Prospective Payment System Proposed Rule. CMS had set the proposed 2006 APC reimbursement rate for OrCel? (APC 9200) at $159.59 per unit. This a significant reduction from the CY 2005 rate of $991.85.

In the previous comment letter, we indicated that OrCel was not commercially available during 2004 and as a result, neither average sales price (ASP) data nor hospital outpatient claims data should have existed for the product. Therefore, the existence of any hospital claims data for OrCel would appear to be an error in a hospital?s claims submissions.

In the absence of either claims or ASP data to support the 2006 OPPS rate setting process for OrCel, we would like to propose the following solution. In the 2005 OPPS Final Rule, CMS established payments rates for certain drugs and biologicals that did not have ASP data associated with it using wholesale acquisition cost (WAC) data. If WAC was unavailable, then 95 percent of the May 1, 2003 AWP was utilized. The AWP for OrCel, as published in Thomson Micromedex Red Book on May 1, 2003, was $1,250. As a result, 95% of the AWP would be $1,187.50.

We believe the methodology, as set forth in the 2005 Final Rule, represents an equitable solution to the rate setting problem and ask that you consider this methodology. Should you have any questions, or wish to discuss this in greater detail, please feel free to contact me at 646.522.1927 or by E-mail at costa.Papastephanou@ortecinternational.com.

Submitter : **Dr. Bruce Cohen** **Date: 09/15/2005**

Organization : **McLean Hospital**

Category : **Psychiatric Hospital**

Issue Areas/Comments

GENERAL

GENERAL

VIA ELECTRONIC MAIL and Regular Mail

September 14, 2005

Mark McClellan, M.D. Ph.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
Mail Stop: C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

RE: CMS-1501-P: Proposed Changes to Hospital Outpatient PPS

Dear Dr. McClellan,

McLean Hospital is a major provider of Partial Hospital Services for the Metro Boston area. We are extremely concerned that the proposed 15% payment reduction to Partial Hospitals may result in significant problems for all Partial Hospital programs, here and elsewhere, and threatens their ongoing existence.

These services are essential to offer a continuum of care that encourages and supports the care of patients in the community and in many cases can help to avoid or delay an inpatient hospital stay. A reduction in these programs could be costly in leading to increased illness and time spent hospitalized for patients.

The 15% payment reduction proposed to begin in January, 2006, will place an additional enormous strain on our programs. We understand that unreliable data from the Community Mental Health Centers is a major reason the rate cut is being proposed by CMS and that CMS would like the CMHC?s to develop a more reliable reporting methodology. That is understandable given some of the variances in the data that CMS has seen over the past few years. However, we believe it would be far better to maintain the current rate structure until a payment methodology which is derived from more reliable data is developed.

Improved data would help providers to design appropriate services that may work better for the patient population and result in a more straightforward reimbursement methodology.

We would be happy to work with your staff to help define these data requirements.

Please do not reduce the rates for Partial Hospital programs for 2006; but rather delay any consideration of a rate cut until a more reliable reporting methodology is devised.
Thank you for considering these comments.

Please let me know if you have any questions.

Sincerely,

Bruce M. Cohen, M.D., Ph.D.
President and Psychiatrist in Chief
McLean Hospital

BMC:rgt

Submitter : Bob Colvin **Date:** 09/15/2005

Organization : Memorial Health University Medical Center

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-437-Attach-1.DOC

Memorial
HEALTH
University Medical Center

September 16, 2005

The Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS –1501– P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: CMS-1501-P – Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment Systems and Calendar Year 2006 Payment Rates; Proposed Rule (70 *Federal Register* 42674).

Dear Administrator McClellan:

Thank you for the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule concerning the Hospital Outpatient Prospective Payment System. Memorial Health University Medical Center (MHUMC) is a 530 bed teaching hospital with Level I Trauma Center status located in Savannah, Georgia.

This letter will focus on the proposed changes to Adjustments for Certain Hospital Categories (pages 42698-701), Changes to OPPS Outlier Policies (pages 42701-702), Transitional Pass-Through Payments (42735), OPPS Payments for Drugs, Biologicals, and Radiopharmaceuticals (pages 42723-732), Inpatient-Only Procedures (pages 42745-746), and Multiple Diagnostic Imaging Procedures (pages 42748-751).

I. Adjustments for Certain Hospital Categories (pages 42698-701)

"Adjustments for Certain Hospital Categories"

At the outset, we continue to be concerned about OPPS payment equity for teaching hospitals. In the initial OPPS Final Rule, published April 7, 2000, CMS stated that it would "conduct analyses and studies of cost and payment differential among different classes of hospitals, including

teaching facilities, when sufficient data under the PPS had been submitted. We will carefully consider whether permanent adjustments should be made in the system once the BBRA 1999 transition provisions expire." (65 Fed. Reg. at 18500). In addition, the Balanced Budget Act of 1997 requires the Secretary to establish adjustments "as determined to be necessary to ensure equitable payments...for certain classes of hospitals." (Section 4523 of the BBA). Current law permits CMS to make these adjustments in a budget neutral manner to the OPPS payments for certain Hospital categories if the Agency determines such adjustments are "necessary to ensure equitable payments." (BBA sec. 4523)

"Rural Hospital Adjustment" Comment

Despite past pronouncements that the Agency would study teaching hospitals' outpatient costs, the proposed rule includes no such discussion. We urge CMS to conduct a regression analysis to determine whether a teaching adjustment is appropriate. We believe one of the analyses should involve examining the reliance of teaching hospitals on pass-through, outlier, transitional corridor, and device-dependent APC payments. If the results suggest that teaching hospitals have depended upon these payments to achieve payment equity relative to other hospital types, we believe a teaching hospital adjustment should be developed and implemented as soon as possible. Outpatient PPS does not include an IME adjustment. We feel an IME adjustment should be implemented for Outpatient PPS as there is an adjustment for Inpatient, Psych, and Rehab PPS.

II. Changes to OPPS Outlier Policies (pages 42701-702)

"Changes to OPPS Outlier Policies"

Outlier payments are an important component of the OPPS because they provide some financial cushion when hospitals treat high cost cases. For CY 2006, CMS proposes to, decrease the outlier payment by reducing the size of the percentage of total outlier payments from 2% of the aggregate total payments to 1%. In order to achieve this reduction, CMS would increase the fixed dollar threshold from $1,175 to $1,575, while keeping the multiplier threshold at its current level of 1.75. The payment percentage would remain the same - - 50%.

"Outlier Payments" Comment

According to CMS, the change in the outlier threshold has a minimal redistributive impact by class of hospital. However, the proposed rule contains no analyses that support its proposal to reduce the outlier pool. Furthermore, it is unclear whether the outlier pool has been overspent or underspent. We urge CMS to publish data on outlier payments before making changes to the outlier payments. We feel the Outpatient policy needs to be consistent with the Inpatient percentage of 80% instead of 50%.

III. Transitional Pass-Through Payments (pages 42717-723, 42735)

"Tansitional Pass-Through Payments for Devices"

The proposed rule states that pass-through payments for the 3 current device categories will expire at the end of December 2005. The costs of these devices will be packaged with the costs of the procedures with which the devices were billed in 2004 (70 Fed. Reg. at 42718). CMS proposes no new device categories for pass-through payments for CY 2006.

"Pass-Through Device" Comment

For 2006, CMS proposes to adjust the median costs for device-dependent APCs to the the higher of the 2006 unadjusted APC median cost (based on 2004 data) or 85 percent of the adjusted median cost on which payment is based for 2005. We would recommend using 100 percent rather than 85 percent of the median cost for 2005. As well as needing more information as to how CMS chose 85%, we are also concerned that current device category descriptors are too broad and preclude some new technologies from qualifying for establishment of a new device category for pass-through payment.

IV. OPPS Payments for Drugs, Biologicals, and Radiopharmaceuticals (pages 42723-732)

"OPPS Payments for Drugs, Biologicals, and Radiopharmaceuticals"

Items that do not have pass-through status, are paid in one of two ways: packaged payment and separate payment. While packaging the costs of items into the payment for the procedure with which they are associated encourages hospital efficiencies, CMS recognizes that expensive and rarely used drugs, biologicals, and radiopharmaceuticals need to be paid separately in order to prevent insufficient payments to hospitals. Thus, under current law, a threshold of $50 per day is applied, so that items whose cost per day is less than $50 are packaged with the procedures with which they are billed and those whose cost exceed $50 per day are paid separately.

CMS proposes to continue pass-through status for 14 drugs in 2006. The MMA provided that for CY 2006, payment for separately payable drugs, biologicals, and radiopharmaceuticals be equal to the average acquisition cost for the drug for that year, subject to any adjustment for overhead costs. This is in contrast to the current payment methodology, which is based on average wholesale price.

"NonPass Throughs" Comment

CMS has decided that the "average" acquisition cost for drugs, and biologicals would be best represented by the average sales price (ASP). CMS is proposing to pay ASP plus 6 percent to cover acquisition costs for drugs and biologicals. For 2006, CMS proposes to add 2 percent of ASP to the payment rates for drugs and biologicals to cover pharmacy handling costs and instruct hospitals to

charge the appropriate pharmacy overhead C-code for overhead costs. CMS proposes to establish three drug-handling categories in 2006 representing drugs with potentially different handling cost requirements (excluding radiopharmaceuticals) as follows: oral, compound, and somewhere in the middle. While we agree that it is appropriate to provide additional payments to hospitals to account for pharmacy overhead and drug handling costs, requiring hospitals to charge separately for pharmacy overhead using these new C-codes would be extremely burdensone and unworkable. Other payers do not recognized C-codes, and this proposal would require that hospitals establish one charging procedure for Medicare and another for all other payers.

V. Inpatient-Only Procedures (pages 42745-746)

"Inpatient-Only Procedures"

Under current OPPS policy, CMS deems certain procedures as "inpatient only" for which hospitals will not receive an OPPS payment if these procedures are performed in the hospital outpatient department. Under the proposed rule, 25 procedures would be taken off the "inpatient only" list.

"Inpatient Procedures" Comment

We believe this list should be eliminated as physicians, not hospitals, determine what procedures should be performed, as well as whether a patient's condition warrants an inpatient admission.

VI. Multiple Diagnostic Imaging Procedures (pages 42748-751)

"Multiple Diagnostic Imaging Procedures"

Currently, hospitals receive full APC payments for each diagnostic imaging procedure noted on a claim, regardless of how many procedures are performed using a singular modality or whether or not contiguous areas of the body are studied in the same session.

"Multiple Diagnostic Imaging Procedures" Comment

CMS proposes to reduce payment in 2006 by 50 percent for the second and subsequent imaging procedures when all the procedures are performed during a single patient encounter and all are within an identified "family" of procedures that are commonly billed on the same day. CMS identifies 11 "families" of imaging procedures by imaging modality and by contiguous body area. What rationale and supporting analysis did CMS consider in choosing to pay only 50 percent for the second and subsequent imaging procedures performed during a single patient encounter? More study is definitely needed before this change is implemented by CMS.

Thank you for considering our remarks on the proposed rule. If you have any questions about our comments, please feel free to contact me.

Sincerely,

Bob Colvin
President and CEO

cc: Amy Hughes, MHUMC

Suzanne Heck, CFO, MHUMC

Submitter : **Dr. Lisa Potts** **Date: 09/15/2005**

Organization : **Washington University School of Medicine**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

I would like to acknowledge CMS's responsiveness in working with cochlear implant providers and manufacturers. The overseeing of adequate Medicare payment rates is so crucial. I realize that there is difficulties created due to the hospital outpatient payment system and in tracking the actual device costs.
As an adult cohlear implant center, many of our patients have Medicare as their primary insurance. It is wonderful that Mediciare does cover cochlear implants. However, a reduction in the reimbursement for the equipment which is below the invoice cost of the device would have dramatic effects on our hospital. It is such a dramtic cut, that our hospital could close to CI surgeries.
The cost effectivenes of CIs has been well-documented in peer reviewed literature and accepted by the medical professional and by insurers.
Many of our patients travel 4-6 hours to our center for treatment because there is so few centers and trained audiologists who can work with cochlear implants. If more centers are forced to reduce their nubmer of CIs or quit offering CIS because it is not cost effective, these patients will have no other options. Hearing loss is a devasting disorder on someone's life and the technology and improvements CIs can offer are amazing. It it would be inconcievable to not have access to this technology.
I am requesting that CMS substitute accurate external device cost data as detemined by the Lewin Group study and recalculate the relative weight of APC 0259. IF that is not possible, please at least consider setting the 2006 OPPS payment no lower than 100% of the 2005 payement rate plus the inflation and other update factors applied to all APCs. Thank you for CMS' recognition of the implact of payment rates on access to care and for your consideration of my comments.
Sincerely, Lisa G. Potts, Ph.D., CCC-A
Washington University School of Medicine

Submitter : **Mrs. Anne-Marie Bell** **Date: 09/15/2005**

Organization : **Southern Maine Medical Center**

Category : **Nurse**

Issue Areas/Comments

GENERAL

GENERAL

Dear Mr.Kuhn,

Apligraf and Dermagraf are unique living human tissue substitutes for the treatment of chronic ulcers. Our outpatient clinic will often use these products with success instead of a more complicated and expensive surgical intervention known as Split Thickness Auto Grafts. The Outpatient clinic will not be able to offer apligraf or dermgraft as the payment to our overall system budget will not be balanced. Please consider correcting the issue with the final rule.

Sincerely,
Anne-Marie Bell RN, BSN, CWOCN

Submitter : Dr. Hussam El-Kashlan **Date:** 09/15/2005

Organization : University of Michigan

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-440-Attach-1.DOC

September 15, 2005

Centers for Medicare and Medicaid Services
US Department of Health and Human Services
Attention: CMS-1501-P

Re: File Code: CMS-1501-P
Issue Identifier: Device-dependent APCs

To Whom It May Concern:

I am a physician in the cochlear implant program at the University of Michigan. Our institution has provided over 1000 cochlear implants to profoundly hearing impaired individuals since the mid 1980's. I am writing to oppose the proposed reduction in payment for cochlear implantation in 2006.

Cochlear implantation has always been a procedure where medical institutions and cochlear implant programs have been unable to reclaim the full cost of providing services. However, the medical community has been so strongly motivated to provide this benefit to deaf individuals that most programs have been allowed to continue functioning. The long-term viability of this approach to cochlear implant services is tenuous at best. Further reduction in reimbursements will have a negative impact on the ability of cochlear implant programs to remain open.

I am sure you are aware of the extraordinary benefits that cochlear implantation can provide to deaf individuals. The cost effectiveness of cochlear implantation is well documented in the medical literature. Several evidence based studies document that this technology is more cost effective than coronary artery bypass grafting and other well accepted medical procedures. In addition, the cost savings to society in reduction of educational costs and long-term welfare benefits are immense.

If the proposed cost reductions are implemented, it is possible that there could be a severe impact on the access of Medicare beneficiaries to cochlear implantation. I would strongly encourage the Centers for Medicare and Medicaid Services to reconsider this proposed reduction and rather seek to gradually improve coverage for this important medical device in future years.

Sincerely yours,

Hussam El-Kashlan, M.D.
Associate Professor
Division of Otology/Neurotology

HEK:bc

Submitter : Dr. H. Alexander Arts **Date:** 09/15/2005

Organization : University of Michigan

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-441-Attach-1.DOC

September 15, 2005

Centers for Medicare and Medicaid Services
US Department of Health and Human Services
Attention: CMS-1501-P

Re: File Code: CMS-1501-P
Issue Identifier: Device-dependent APCs

To Whom It May Concern:

I am a physician in the cochlear implant program at the University of Michigan. Our institution has provided over 1000 cochlear implants to profoundly hearing impaired individuals since the mid 1980's. I am writing to oppose the proposed reduction in payment for cochlear implantation in 2006.

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If the proposed cost reductions are implemented, it is possible that there could be a severe impact on the access of Medicare beneficiaries to cochlear implantation. I would strongly encourage the Centers for Medicare and Medicaid Services to reconsider this proposed reduction and rather seek to gradually improve coverage for this important medical device in future years.

Sincerely yours,

Hussam El-Kashlan, M.D.
Associate Professor
Division of Otology/Neurotology

HEK:bc

Submitter : **Ms. Amanda Hopkins-Alexiadis** **Date: 09/15/2005**

Organization : **Baystate Health System**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See attached letter

CMS-1501-P-442-Attach-1.DOC

Baystate Health System

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VIA ELECTRONIC MAIL AND OVERNIGHT DELIVERY

September 14, 2005

Mark B. McClellan, MD, PhD, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
Mail Stop: C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

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RE: CMS-1501-P: Proposed Changes to the Hospital Outpatient PPS

NOTE: "Partial Hospitalization" Comments

Dear Dr. McClellan:

As one of New England's largest health care systems, Baystate Health System appreciates the opportunity to provide comments on the "Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates" as published in the July 25, 2005 *Federal Register*.

We are providing comments that specifically pertain to the proposed partial hospitalization (PHP) and community mental health issues.

About Baystate Health System

Baystate Health System, based in Springfield, Massachusetts, is one of New England's largest health care systems with approximately 9,000 employees, and consists of three member hospitals – Baystate Medical Center in Springfield, Franklin Medical Center in Greenfield, and Mary Lane Hospital in Ware; as well as the Baystate Visiting Nurse Association & Hospice. In addition, the not-for-profit health system features a diverse array of physician practices and ancillary health care services serving communities throughout Western Massachusetts.

As the flagship hospital of Baystate Health System, Baystate Medical Center in Springfield, MA is the region's only tertiary care referral medical center and Level 1 Trauma Center, and is accredited as "one of the highest-rated hospitals in the country" by the Joint Commission on

Accreditation of Healthcare Organizations. The nearly 600-bed teaching hospital is the Western Campus of Tufts University School of Medicine, and serves as a regional resource for specialty medical care and research, while providing comprehensive primary medical services to the community.

Franklin Medical Center in Greenfield, MA, a member of Baystate Health System, provides high quality inpatient and outpatient services to communities in Franklin and Hampshire counties and Southern Vermont. The Birthplace, Cardiopulmonary Services, outpatient surgical services, and the Medical/Behavioral Unit are some of the specialized programs available at Franklin Medical Center.

Partial Hospitalization (PHP) – specifically – has long been a level of psychiatric care offered by both Baystate Medical Center and Franklin Medical Center. Together, our BMC and FMC PHP programs serve annually over 500 individuals and provide over 4,600 patient care PHP visits. The Baystate Health System PHP programs are two of only *a small handful* of PHP programs in Western Massachusetts and serve a tremendous need for patients suffering from acute psychiatric and behavioral health disorders.

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Franklin Medical Center's PHP is ***the only partial hospitalization program available to beneficiaries in Franklin County.*** As a rural community, Franklin County has a higher incidence of mental health issues serving a wide geographic area. As a community hospital, Franklin Medical Center is already "distressed" having received supplemental state funding in recognition of this and has already pared down its behavioral health services.

Both the BMC and FMC partial hospital programs offer much needed mental health services to individuals in a ***less restrictive*** and ***more cost effective treatment*** setting. Because our services are available, patients are admitted who require a "step down" from inpatient psychiatric care which results in shorter and more appropriate inpatients lengths of stay; or individuals can avoid a more costly and restrictive inpatient psychiatric admission because our program provides an appropriate "diversion" from this higher level of care.

Baystate Health System has serious concerns with Proposed Partial Hospital Changes.
We have serious concerns that the proposed changes to the outpatient prospective payment system (PPS) will have a negative affect on our partial hospitalization programs and our ability to be able to provide this service. As a provider, we are committed to finding ways to ensure that our patients have access to this essential level of care, however, our resources are limited. In addition, partial hospitalization capacity in the region remains a concern. We are very concerned about the impact of these changes to other PHP's in the region. Many ***partial hospital programs have been closed*** over the years and our services along with only a handful of other PHP's remain.

The reimbursement for behavioral health services nationwide and in the Commonwealth of Massachusetts, in particular has dramatically declined in the past several years to the point where most providers of behavioral health services can barely cover their costs. In most cases, medical center-based behavioral health programs, such as Baystate's, consistently ***do not cover their costs.*** With this reduced, inadequate level of reimbursement, these services must be subsidized

by other medical center operations or forced to close. With CMS' proposed changes in reimbursement for partial hospitalization, it is likely that even fewer partial hospital programs will be available to patients who require and truly deserve this less restrictive and valuable level of care.

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Medicare patients represent approximately 20% of our BMC PHP patients but almost 32% of our patients at FMC. The projected annual financial impact of these changes on our Baystate programs could be ***as much as $54,000***: $16,000 for BMC and over $38,000 for FMC. This amount may not seem like a large loss, however, the BMC and FMC PHP programs just barely cover their direct costs but do not cover their total costs. A reduction in reimbursement will ensure that these programs can no longer cover even their direct costs. Overall, behavioral health services at Baystate Health System lose approximately ***seven million dollars ($7M)*** each year with BMC losing five million ($5M) and FMC losing over two million ($2M). Clearly, any reduction in reimbursement to any of our behavioral health programs – in this case partial hospitalization -- is untenable.

ISSUES OF CONCERN

Like our counterparts nationwide and in the Commonwealth, we have several areas of concern and respectfully request reconsideration by CMS of its intentions to implement these changes until further comments, analysis and thoughtful evaluation can be conducted:

- The current methodology for determining the PHP rate is in flux.

  We understand CMS considered various approaches in the 2006 proposed rule in dealing with the complexities of the historical cost data supplied by hospital and community mental health center (CMHC) providers of the partial hospitalization benefit. Hospital affiliated PHP's and community based providers are very different. We also understand that the range of data provided by the CMHC's throughout the last five years -- from a high of $1,037 per diem cost to a low of $143 per diem -- has made it difficult to determine actual costs.

  Given the medical and clinical intensity of the partial hospitalization, we do not understand how this benefit could possibly be provided for $143. This figure raises serious questions about the *accuracy* of the data reported on CMHC cost reports. PHPs are required by regulation to provide a program of active treatment which includes at least three individualized treatment sessions per day, in addition to appropriate individual therapy and treatment planning. This level of intensity closely mirrors the care provided in an inpatient treatment setting. If partial hospitalization did not exist, beneficiaries would be hospitalized.

  We understand that the rationale for the CMS proposed 15% rate reduction in the rate (from $289 to $242.65) states that CMS believes this will recognize the decrease in the median per diem costs in both the hospital and CMHC data and also reduce the risk of any adverse impact on access to these services that might result from a large single-year rate reduction. However, CMS further states that you will continue to work with CMHCs to improve their reporting so that payments can be calculated based on better empirical data. If it is recognized that the CMHC's reporting process needs improvement, then we

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<#>A 15 % decrease in the per diem rate will negatively impact not only our programs but most importantly PHP beneficiaries and is an untenable variance in the payment rate.¶
[insert]¶
<#>The methodology for the proposed 2006 PHP reimbursement rate does not adequately account for all important variables.¶
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RECOMMENDATIONS¶
We respect the thought and effort that has gone into the determination of the proposed reimbursement rate for partial hospitalization for calendar year 2006, however we respectfully request that the following recommendations be considered: ¶
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respectfully note that the rate reduction should be reevaluated until better data is indeed available.

- A 15 % decrease in the per diem rate will negatively impact not only our programs but most importantly PHP beneficiaries and is an untenable variance in the payment rate. A PPS system is not designed to endure significant adjustments every year based on historical costs. Changes of the magnitude of 15% undermine the basis of the system. Providers and payers alike need to be able to rely on a predictable methodology for determining payment that will allow the PHP benefit to be available to Medicare beneficiaries in a stable way. This methodology needs to be predicated on reliable data.

- The methodology for the proposed 2006 PHP reimbursement rate does not adequately account for all important variables. The volatility in the CMHC data continues to be inadequately explained. There are many administrative costs (transportation, food) that are not Medicare-reimbursable. But these costs are real costs to the provider and need to be considered as payers and providers analyze the fiscal realities of providing the benefit. There are also highly prescriptive administrative and regulatory responsibilities that providers must meet in order to offer the benefit and which also contribute significantly to costs. In the new era of Medicare *inpatient* psychiatric prospective payment, it will be even more important that there be a *viable* alternative to hospitalization. Partial hospitalization *is* that alternative.

RECOMMENDATIONS

We respect the thought and effort that has gone into the determination of the proposed reimbursement rate for partial hospitalization for calendar year 2006; however we respectfully request that the following recommendations, which are also being proposed by our colleagues in other programs, behavioral health and psychiatry alliances, and regional and national provider associations, be considered:

- **Allow the time and resources necessary to fully develop an adequate payment methodology, we propose that the 2006 PHP payment rate remain the same as the 2005 rate - - $281.33.**

- **Consider using inpatient costs per day as the basis for the PHP median cost per diem.**

- **Further develop a cost method that uses, as an example, a three-year rolling average of the CMHC PHP cost per diem.**

- **Review and consider revising the various forms and worksheets used by CMHC's to report data.** For example: **CMHC cost report form (CMS-2008), settlement worksheet D on the CMS-2088 and the CMHC Provider Statistical & Reimbursement Report** ("PS&R") Report Type: 76P.

In conclusion, on behalf of the beneficiaries we *all* serve, we urge you to *not* reduce the rates for Partial Hospital programs for 2006, and delay any consideration of a rate reduction until a more reliable reporting methodology is devised. We very much appreciate your consideration of our concerns and your willingness to review our comments and recommendations. Thank you.

Sincerely,

Benjamin Liptzin, MD
Chairman – Department of Psychiatry

Amanda Hopkins-Alexiadis
BHS Director of Behavioral Health
Neurosciences and Rehabilitation Services

CC:
Mark R. Tolosky, President and CEO – Baystate Health System
Trish Hannon, Senior Vice President – BHS; Chief Operating Officer - BMC
Michael Skinner, President – Franklin Medical Center
Karen Moore, Chief Operating Officer - FMC
Steven Bradley, Vice President, Government and Community Relations - BHS
Representative Richard E. Neal
Representative John W. Olver
Senator Edward M. Kennedy
Senator John F. Kerry

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Submitter :

Date: 09/15/2005

Organization : **American Academy of Neurology**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See attachments.

CMS-1501-P-443-Attach-1.DOC

CMS-1501-P-443-Attach-2.PDF

AMERICAN ACADEMY OF NEUROLOGY

1080 Montreal Avenue
St. Paul, Minnesota 55116

tel: 651.695.1940
fax: 651.695.2791

www.aan.com

September 15, 2005

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services

Re: Hospital Outpatient Prospective Payment System 2006 Payment Rates; CMS 1501-P

Dear Dr. McClellan

The American Academy of Neurology (the "AAN" or the "Academy") appreciates this opportunity to comment on the proposed rule for the 2006 hospital outpatient prospective payment rates, as published in the July 25, 2005 Federal Register.

The AAN would like to comment on the following issues:

- APCs for EEG services
- MEG services
- Payment for IVIG

APCs for EEG Services

The proposed rule would reduce payment for APC 214 (EEG) from $129.85 to $67.37 – a reduction of almost 50%. CPT Codes mapped to this APC include 95824 (EEG for brain death) with a median charge of $124.63 and 95829 (surgery electrocorticogram) with a median charge of $50.81. Other CPT Codes mapped to this APC are 95954 with a median charge of $65.40 and 95957 with a median charge of $68.51.

The mapping of CPT Code 95824 to this APC violates the "two times" rule since the median charge for that code is over two times as much as the median charge for CPT Code 95829. We believe it would be more appropriate to map 95824, which clearly has higher charges associated with it, to APC 213 which is reimbursed at a rate that is much closer to the median charge for that service.

MEG Services

AAN requests that CMS accept the recommendation of the APC Advisory Committee to maintain the current New Technology APC assignments of the three Magnetoencephalography (MEG) CPT Codes 95965 – 95967 in 2006. In the proposed rule all of the MEG codes were moved into APC 0430, Nerve and Muscle Tests Level IV, which has a payment level of $676.75. The current APC assignments and payment rates for MEG services are: Code 95965 in APC 1528 - $5,250, Code 95966 in APC

1516 - $1,450 and Code 95967 in APC 1511 - $950. In addition, under the proposed rule, the status indicator for each code would be changed from "S" to "T" so that when one of the procedures is performed in combination with another procedure, payment would be reduced by 50 percent.

In April 2002, the AAN and the American Society of Neuroradiology prepared a cost analysis of MEG services requesting placement of the codes in separate New Technology APCs (copy enclosed). This data shows that the cost of these services far exceeds the proposed $676.75 payment level. AAN has also reviewed the data CMS used to assign the MEG services to APC 0430. In 2004, there were only ten single claims submitted for MEG services (7 for 95965 and 3 for 95966), an inadequate number to make a reasonable estimate of hospital median costs. Also, the Academy is concerned that the data itself is not correct. This may be due to hospitals setting charges that reflect lower cost imaging services as well as incorrect coding.

MEG is a non-invasive procedure that essentially superimposes seizure activity or evoked sensory activity onto MRI images of the brain. CPT Code 95965 is typically provided to patients with intractable epilepsy considering epilepsy surgery. The procedure enables the physician to determine if the seizure activity is focal or generalized and if focal, if the focus is located in an area where surgical removal is feasible. CPT Codes 95966 and 67 are used to identify functional areas of the brain, such as hearing, vision, movement, and sensation, prior to surgery to remove a tumor or epileptic legion. The surgeon uses the MEG results to determine where to operate to minimize patient risk and avoid the most valuable functional areas of the brain.

At the August 18, 2005 meeting of the APC Advisory Committee three clinicians that provide MEG services presented testimony raising concerns with the proposed APC assignment. As a result of these presentations, the Committee voted to recommend that CMS retain the current new technology APC levels for 2006. AAN strongly endorses this recommendation. The Academy also urges CMS to maintain the status indicator of "S" for these codes since the current payment rates reflect appropriate differentials in the costs of performing these services. Finally, the APC Advisory Committee recognized the need to gather more accurate cost and charge data from hospitals providing MEG services. AAN is committed to working with CMS to collect this data, so that an appropriate APC rate for MEG services can be established in future years.

Payment for IVIG

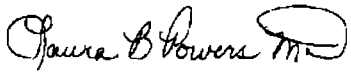
As a result of the transition to the new ASP plus 6% methodology for reimbursing outpatient Part B drugs, reimbursement for IVIG will decrease from $80.68/gram to approximately $39 for lyophilized IVIG and $57 for the non-lyophilized version. We are informed that the cost to most hospitals of acquiring IVIG is considerably higher than the payment amount based on the ASP. This may be due to the fact that there is a currently a scarcity of IVIG.

We have heard from members that the decrease in payment for IVIG provided in the physician office resulting from implementation of the ASP plus 6% rate has made it difficult, if not impossible for physicians to provide this drug in the office setting without incurring a loss. As a result, patients are being referred to hospital clinics for this drug. Thus, in some communities, hospital clinics have become the provider of last resort. However, if hospital reimbursement also drops, as it would under the proposed rule, and hospitals must provide the drug for less than their acquisition costs, they may also cease providing it. This could create serious access problems for patients who depend on this drug to treat serious and often life-threatening neurological conditions who must receive their IVIG in a facility setting due to the possibility of reactions.

We urge that CMS carefully consider whether the proposed reductions in reimbursement for IVIG will result in loss of access to this important drug.

We thank you for the opportunity to comment on this proposal. If you have questions please contact Amanda Bettmann at (651) 695-2718 or abettmann@aan.com.

Sincerely,



Laura Powers, MD
Chair, AAN Medical Economics and Management Subcommittee

Attachment: 2002 MEG Letter

April 24, 2002

Ms. Cindy Read
Director
Medicare Contractor Integrity and Performance Group
S2-21-27
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, MD21244

Ms. Read:

In follow-up to our meeting with you on February 19, 2002 concerning the APC placement of Magnetoencephalography (MEG) services, this letter will provide you with a revision of the cost estimates presented and answers to the questions raised. We have also collected private payer information, which you requested. We believe that this data justifies a change in the APC placement of MEG and ask that this be done as soon as possible.

Currently, the three MEG CPT codes (95965, 95966, and 95967) are in the new technology APC 0972, which pays $150. We ask that you reassign 95965 to APC 0719 for services costing between $3,000-3,500 and codes 95966 and 95967 to APCs 0716 ($1750 - $2000) and 0713 ($1000 - $1250), respectively. We are also asking that these codes not be subject to the multiple procedure payment reduction (T status). If the CPT codes are placed in appropriate APCs based on actual costs, the 50% payment reduction for multiple services should no longer apply.

During our meeting concern was expressed that there would be a low volume of MEG services provided to Medicare beneficiaries. While we agree that this will be the case we do believe that it is critically important for Medicare to assign these services to the appropriate APCs. The Medicare population most likely to need MEG services are individuals who are eligible by virtue of their disability. Intractable epilepsy would be the most common reason. Without adequate payment for the service, this population would not have access to this important technology. In addition, many private insurers look to Medicare as a national model for guidance on coverage and payment. We are concerned that continuation of the current rate could jeopardize access to MEG services for the non-Medicare population as well.

Background

MEG is a non-invasive procedure that superimposes seizure activity or evoked sensory activity onto MRI images of the brain. Prior to epilepsy surgery, MEG films showing epileptic activity in relationship to cerebral anatomy enable physicians to see if seizure activity is concentrated in one or a few locations to

determine if surgical intervention is feasible. In addition, for all patients undergoing neurosurgical procedures, the MEG is used to locate the regions of the patient's brain responsible for perception of sensation, movement, vision and hearing relative to the surgical target.

Three new CPT codes were established for MEG services in 2002:

95965 – Magnetoencephalography (MEG), recording and analysis; for spontaneous brain magnetic activity (eg, epileptic cerebral cortex localization)

95966 – for evoked magnetic fields, single modality (eg, sensory, motor, language, or visual cortex localization)

95967 – for evoked magnetic fields, each additional modality (eg, sensory, motor, language, or visual cortex localization) (List separately in addition to code for primary procedure)

CPT code 95965 is a service provided to patients with intractable epilepsy (uncontrolled seizures) as part of an epilepsy surgical evaluation in hospitals with specialized epilepsy centers. These patients typically are considering epilepsy surgery following multiple unsuccessful courses of medication therapy. Many of these patients have had uncontrolled seizures for over ten years and a variety of drug therapies have not been successful. The challenge in a patient with epilepsy is to determine if the source of seizure activity is focal or generalized, and if focal, if the focus is located in an area where surgical removal is feasible.

The MEG records the magnetic fields of the brain. Usually an EEG is performed simultaneously and billed separately. The recorded magnetic fields are analyzed to determine the sources of their activity and mapped onto the patient's MRI. This enables the physician to determine if the epileptic activity is concentrated in one or a few focal regions and whether those regions are possible candidates for surgical resections. Information from this mapping can also be used to guide the placement of intracranial electrodes for further video/EEG monitoring prior to the definitive epilepsy surgery. The non-invasive nature of the procedure, and high temporal and spatial resolution of the image achieved make this method of neuro-imaging especially valuable for presurgical localization of epileptic activity.

CPT codes 95966 and 67 are non-invasive diagnostic procedures recording biomagnetic activity from inside the brain to identify functional areas of the brain that are then mapped on an MRI or CT scan prior to surgery to remove a tumor or epileptic lesion. The MEG is used for somatosensory, auditory, visual, language or functional mapping to determine the risk of neurological damage if surgery is to occur. If surgery is elected, the surgeon can use the map to determine where to operate to minimize patient risk and avoid the most valuable functional areas of the brain. CPT code 95966 is used for testing a single

sensory modality while 95967 is coded with 95966 for testing additional modalities.

The MEG codes are currently assigned to a single APC that pays well below the cost of any of the three services. The codes are subject to the multiple procedure reduction. It is unclear what, if any, data was used to make this assignment.

Explanation of Cost Data

Information on the costs of providing MEG services is summarized in the attached chart. The capital equipment has a price of approximately $2 million and is assumed to have a 7-year useful life. The annual maintenance cost is $100,000. The other large fixed cost item is $22,000 per year for liquid helium, which is needed to cool the equipment regardless of the number of services provided. (Smaller amounts of gaseous helium are also needed, but its utilization is dependent upon the volume of services provided.) Supply costs for the codes are minor, totaling approximately $70 for 95965 and less than $50 for 95966 and 95967.

As MEG services are provided by both neurologists and neuroradiologists, the clinical staff utilized will vary depending on whether the MEG is part of a hospital's neurology or radiology department. Neurology departments will utilize Registered EEG Technologists (R.EEG T.) with a labor rate of $.47 per minute. Radiology departments will utilize Ph.D. neurophysiologists, whose labor rate is $1.10 per minute. Based on the current number of MEG units in operation and those being installed this year, 70% are in neurology departments. For this reason we used a blended labor rate of $.69, based on the existing 70/30 split.

For overhead, we used a rate of 30%. This represented the average rate for the hospitals we surveyed.

The number of MEG services per year vary significantly by code. In our cost estimate, we assume a utilization rate that is higher than all the hospitals we surveyed. We believe our assumed utilization rate is very reasonable given the actual utilization rate of the hospitals with more mature MEG services and the limited number of patients who need these highly specialized services. Our cost estimate is based on 210 total services provided a year, broken down as follows: 120 –95965, 60 – 95966, and 30 – 95967.

The time per test also varies significantly by code. CPT code 95965 – the MEG service for epilepsy surgery evaluation requires a significant amount of time. The test itself takes approximately 3 hours; this includes pre-test activities including room and equipment set-up, positioning the patient, demagnatizing the patient, and measuring the patient's head and position. Typically, the test records at least three ten minute periods of data where measurements of the head are

taken before and after each recording period to assure that no movement occurred. The tech monitors the incoming data and views the patient during the entire procedure by video camera. The analysis of the data and overlay of the results on the MRI take another 4 hours of technologist's time. This post-procedure data processing utilizes various techniques to localize the sources of epileptic events within the frame of the detector array and to superimpose the source locations on the patient's MRI data for interpretation.

CPT code 95966 takes a significantly shorter period of time. The test itself takes 1.8 hours. Similar to the test explained above, the patient must be positioned properly, demagnetized and his head must be measured. Each modality has a specific set of instructions and most require positioning of specialized equipment to evoke the response. For example, to perform somatosensory testing, the tech attaches small pneumatically activated stimulus devices to the patient's thumbs and index fingers and demonstrates the feel of the stimulus. The patient is instructed to stay alert by silently counting the number of stimuli. Pressure pulses are applied to the digits one at a time in order to evoke somatosensory responses. The tech monitors the patient via video camera and the incoming data during the entire procedure. Data analysis takes about two hours. During this time techniques are used to localize the sources of the sensory evoked responses for each digit within the frame of the detector array, calculations are made and source locations are superimposed on the patient's MRI data for interpretation by the physician.

When additional sensory modalities are tested 95967 would be coded. It takes approximately 70 minutes for patient set-up and to do the actual test. Since 95967 would only be performed if 95966 had been performed on a patient, less time is needed to position, measure and demagnetize the patient. CPT code 95967 includes 80 minutes of clinical staff time for post-test analysis including identification of source locations, calculations and superimposing the data on the patient's MRI.

Based on the cost data explained above we have calculated a total cost/test for each of the codes:

95965 - $4,054

95966 - $2,417

95967 - $1,570

Private Payer Data

At your request we did survey several centers seeking private payer information on MEG services. We collected data from over 30 private insurers, including Aetna, CIGNA, Kaiser, United Healthcare, and many Blue Cross/Blue Shield

plans from across the country. Prior to 2002 claims were submitted using miscellaneous codes with documentation explaining the epilepsy surgery test and the somatosensory mapping test (attached is the documentation used by Henry Ford Hospital when billing for these services prior to 2002).

For the service that is now defined as 95965, the average payment for 2000 and 2001 was $2753 and the median payment was $2791. For the service that is now defined as 95966 the average payment for each service in 2000 and 2001 was $1053 and the median payment was $1143.

Recommendation

As CMS has specified that it will pay 82% of costs, we are requesting that CPT code 95965 be assigned to an APC covering costs of $3324 (0719). Similarly, Codes 95966 and 95967 should be assigned to APCs covering costs of $1981 (0716) and $1286 (0713), respectively. We are also asking that these codes not be subject to the multiple procedure reduction. If they are to be placed in separate APCs that closely reflect their actual costs, this reduction would not be appropriate. Over the coming year we would also like to work with you and your staff to determine a permanent APC assignment for MEG services.

We would be happy to meet with you again to discuss these specialized services and the cost estimates we have developed. Please feel free to contact Gregory L. Barkley, MD with any questions at 313-916-3922.

Sincerely,

Gregory L. Barkley, MD
American Academy of Neurology

Howard A. Rowley, MD
American Society of Neuroradiology

cc. Paul Rudolph M.D., J.D.
Terry Deuctsh

Assumptions

Base System Cost	$2,088,977.00			
Amortization Period (Years)	7			
System Cost/Year	$298,425.29			
Helium cost/per year, fixed	$22,000.00			
Maintenance Cost/Year	$100,000.00			
MEG Technician Cost/Minute	$0.69			
Overhead (30 percent)	0.3			
Test CPT Code	**95965**	**95966**	**95967**	
Tests/Year	120	60	30	
Hours/Test	3.00	1.8	1.16	
		6		
Test Hours/Year	360	108	34.8	
Total Test Hours/Year				502.8
System Cost/Test Hour				$593.53
Helium Cost/Test Hour				$48.08
Maintenance Cost/Test Hour				$198.89
Base Cost/Test Hour				$918.96
Base system costs/Test	**$2,756.88**	**$1,654.13**	**$1,065.99**	

Technician Costs			
Tech Test Cost/Test	$124.20	$74.52	$48.02
TechReport Time/Test (min)	240	120	80
Technician Report Cost/Test	$165.60	$82.80	$55.20
Total Technician Costs/Tes	**$289.80**	**$157.32**	**$103.22**

Ancillary Supplies Cost/Test			
Helium Gas	$4.68	$2.12	$0.88
2 inch Kling wrap	$0.38	$0.38	$0.38
Assembly coil HRS (green)	$0.40	$0.40	$0.40
Assembly coil HRS (red)	$0.40	$0.40	$0.40
Blank ink jet cartridge	$4.50	$4.50	$4.50

Carbon dioxide, gas USP	$1.39	$1.39	$1.39
Color printer cartridges	$2.94	$2.94	$2.94
Conductive jelly, 5g	$0.08		
EKG leads, disposable	$0.08		
Exam table paper	$0.02	$0.02	$0.02
Flat coils HRS	$2.67	$2.67	$2.67
Fuji 4mm 90m data cartridge	$1.87	$1.87	$1.87
Gauze, sterile 4x4 (10 pack)	$1.47		
Gloves, non-sterile	$0.12	$0.12	$0.12
Magneto-optical disk, 128 gigabyte	$22.50	$2.25	$2.25
Photographic printer paper	$1.87	$1.87	$1.87
Pillowcase, disposable	$0.32	$0.32	$0.32
Printer toner cartridge	$18.40	$18.40	$18.40
Promold hearing aid inserts	$8.00	$8.00	$0.00
Tape	$0.02	$0.02	$0.02
White copy paper	$0.00	$0.00	$0.00
Swab, alcohol	$0.02	$0.02	$0.02
Ancillary Supplies Total Co	**$72.13**	**$47.67**	**$38.43**
Total Direct Cost/Test	**$3,118.81**	**$1,859.12**	**$1,207.64**
Overhead	**$935.64**	**$557.74**	**$362.29**
Total Cost/Test	**$4,054.45**	**$2,416.86**	**$1,569.93**

Submitter : **Ms. Michele Beauvais** **Date: 09/15/2005**

Organization : **William Beaumont Hospital**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

1) Which cost to charge ratio will be used as the basis of payment: A) the aggregate cost center on our cost report that contains our Radiopharmacy department in addition to other departments such as Nuc Med Imaging or B) will the individual department be extracted from the other departments that are grouped into the same CMS cost center?

2) Which time period will the cost to charge ratio be used for interim payments? The two obvious choices are the last filed cost report (2004) or the last audited cost report (2001)?

3) Will the services paid using the cost to charge ratio as the basis for this special cost based reimbursement be subject to final settlement on the cost report? To say it another way, we will be paid during the interim using the most available cost report data to set as our cost to charge ratio but will we on the back end settle with Medicare on the cost report when we calculate that year's cost to charge ratio?

Submitter : Dr. Peter Wiggin **Date:** 09/15/2005

Organization : DPM

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Aplilgraf is an advanced bioengineered tissue based therapy indicated for treatment of venous leg ulcers and diabetic foot ulcers. It is an important element of advanced wound care, shown to speed up healing rates and reduce amputations in severely affected patients. It is the only tissue based therapy approved for treatment of venous ulcers. Please correct the proposed ruling.

Submitter : Dr. MARK WINTER **Date:** 09/15/2005

Organization : Dr. MARK WINTER

Category : Device Industry

Issue Areas/Comments

GENERAL

GENERAL

I AM WRITING IN REGARDS TO DEVICE-DEPENDENT APCS REGARDING COCHLEAR IMPLANTS. PRIOR INCREASES IN PAYMENT TO COCHLEAR IMPLANT HOSPITAL/OUTPATIENT FACILITIES HAS BEEN APPRECIATED AND HAS HELPED MY PATIENTS TO RECEIVE NEEDED CARE. PLEASE RECONSIDER THE REDUCTION IN PAYMENT AS IT WILL NEGATIVELY IMPACT THE PEOPLE YOU ARE SERVING.

RESPECTFULLY SUBMITTED, MARK L WINTER, MD

Submitter : Mrs. Carmen Landry **Date:** 09/15/2005

Organization : Magnolia Speech School

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-447-Attach-1.DOC

RE: Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates

File Code: CMS-1501-P
Issue Identifier: Device-dependent APCs

We are concerned that CMS has proposed a reduced payment for cochlear implantation to $21,739 in 2006 from $25,307 in 2005. This would have a severe impact on Medicare and Medicaid beneficiary access. There are already such a limited number of centers that take Medicaid since they end up losing money on these patients. Currently in Jackson, Mississippi, Dr. Jeffery Carron, the otologist at University Medical Center who routinely received Medicaid patients for cochlear implants is no longer there. This center is now without a cochlear implant surgeon so referrals are being made to Dr. James House, who in the past has limited implanting Medicaid patients to no more than one every month or couple of months due to reimbursement rates being so low. In the aftermath of hurricane Katrina, other implantation sites have had to close, making the number of centers even more limited in our area and extended area. Several children at our facility were implanted in the New Orleans area, or have had testing performed there.

Early intervention is essential for children to receive the extraordinary benefits of cochlear implantation. Here at the Magnolia Speech School, cochlear implants have become a large part of our students' lives. With a decrease in Medicare coverage, many of the children will have minimal funds and possibility become unable to attend our facility. We pride ourselves on giving exceptional care to each of our students allowing them to have lives with the accompaniment of sound. We request that CMS substitute accurate external device cost data and recalculate the relative weight of APC 0259. We in the Jackson area appreciate you taking the time to view and consider our comments. Thank you!

Sincerely,

The Magnolia Speech School Audiology Staff,
Alicia Swann, MCD, CCC-A
Gina Rusell, MS, CCC-A
Carmen Landry, MA, CF/A

Submitter : Ms. Denise Merlino **Date:** 09/15/2005

Organization : Society of Nuclear Medicine

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

Comments are in attachment.

CMS-1501-P-448-Attach-1.PDF

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September 15, 2005

Submitted Electronically: http://www.cms.hhs.gov/regulations/ecomments

Administrator Mark McClellan M.D. PhD
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
ROOM 445-G
200 Independence Avenue, S.W.
Washington, DC 20201

ATTN: FILE CODE CMS-1501-P

Re: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; Proposed Rule

Dear Administrator McClellan:

We are writing in response to the proposed 2006 Hospital Outpatient Prospective Payment System (HOPPS) Rule, 70 Fed. Reg. 42673, July 25, 2005. The Society of Nuclear Medicine (SNM) representing more than 14,000 physicians, scientists, pharmacists and nuclear medicine technologists appreciates the opportunity to provide comments to assist the Centers for Medicare and Medicaid Services (CMS) in further refining the HOPPS. The SNM is committed to carefully reviewing and providing manageable options for all stakeholders. We appreciate CMS willingness to understand and account for the unique and varying attributes of radiopharmaceuticals and processes used in Nuclear Medicine procedures provided to Medicare beneficiaries. We look forward to working with the CMS collaboratively as you respond to our concerns and recommendations herein.

Additionally, we appreciated the opportunity to recently meet with CMS, along with the ACR and AMI, regarding appropriate reimbursement for diagnostic CT when performed in conjunction with PET/CT (CPT 78814-16). The issue is summarized in our letter to Dr. Simon dated July 11, 2005 which is attached (Addendum A). Our specific concern is appropriate reimbursement for a diagnostic CT study when acquired as part of the same data set as for the PET/CT study itself (what we have referred to as a "*single CT acquisition*". Oncology practice is changing as the clinical usefulness of PET/CT technology is learned and applied. Although not yet widely adopted, increasing numbers of facilities are capable and currently performing *single CT acquisition* when their referring physicians order diagnostic CT (S) and PET/CT. At that meeting, we agreed that most of the technical resources for acquiring diagnostic CT data were the same as for the CT for attenuation correction and anatomical localization of the PET/CT, when only *a single CT acquisition* is performed. However, there are added costs for acquiring the diagnostic CT data such as for the contrast agent and appropriate nursing and technical personnel. These were not assumed for any previous cost determination, such as for the PEAC, for doing a PET/CT. These costs should be reflected in any new payment scheme proposed. Further, there should be consideration given on

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how to properly code for a diagnostic CT when performed as single acquisition with a PET/CT. The Society will work with CMS and our colleagues from AMI and ACR on this issue.

Our comments on the Rule will address proposed changes to radiopharmaceuticals, radiopharmaceuticals handling costs, APC assignment of PET/CT CPT code 78814-6, Packaging issues and CPT relocation issues.

Non-Pass Through Radiopharmaceuticals

Proposed Changes to Radiopharmaceutical (RP) Payment Policy in 2006

CMS intends to implement "a temporary 1-year policy for CY2006 to pay for radiopharmaceutical agents that are separately payable in CY 2006 based on the hospital's charge for each radiopharmaceutical agent adjusted to cost." The SNM agrees with the implementation in CY2006 of this one-year temporary policy, with the understanding that the CMS intends to use the hospital general cost to charge ratio (CCR) and not a department specific CCR to make this adjustment. Radiopharmaceutical revenue codes 0343 and 0344 were implemented by the American Hospital Association effective October 2004. We intend to review the effect these codes could have on the department specific cost to charge ratios in the future. However, at present we would not support use of the department specific CCR for radiopharmaceuticals until we can analyze adoption and impact, which we would not expect to be fully realized for at least two years from implementation date.

We are also concerned about the effect of cost compression using the CCR. This will result in under payment for more expensive radiopharmaceuticals. Table 1 is a comparison of CMS hospital median cost, which CMS would believe is representative of hospital charges reduced to cost, and the GAO Acquisition Cost Survey from the same time period. As radiopharmaceutical costs increase, the differences between actual cost and CMS derived cost increase exponentially. We believe this is from cost (really *charge*) compression. We ask that CMS recognize this and consider measures to address this phenomenon. As an extreme example, if the general CCR for a hospital is .389 and acquisition cost alone for a therapeutic radiopharmaceutical such as Zevalin or Bexxar is $22,000, it is not likely that hospitals will set their charges at $56,555 for a single radiopharmaceutical. If hospitals charge what we believe is an average charge of $39,000 or less, this same hospital would receive only $15, 171, which would be substantially less than for their acquisition costs alone.

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Table 1 CMS median cost compared to GAO acquisition median cost

HCPCS	Description	2004 CMS Median Unit Cost‡	2004 GAO Median Purchase Price†	% Difference
A9500	Technetium Tc 99m Sestamibi, per dose	$70.61	$76.47	-8%
A9502	Technetium Tc 99m Tetrofosmin, per dose	$63.89	$67.59	-5%
A9505	Thallous Chloride Tl 201 per mCi	$21.82	$15.49	41%
A9507	Indium In 111 Capromab Pendetide, per dose	$747.47	$1,841.23	-59%
A9521	Technetium Tc 99m Exametazime, per dose	$236.06	$456.30	-48%
C1083	Yttrium 90 Ibritumomab Tiuxetan, per dose	$11,372.45	$19,516.70	-42%
C1775	Fluorodeoxyglucose (FDG) F-18, per dose (4-40 mCi)	$210.96	$272.80	-23%

‡ Median Costs for Drugs, Biologicals and Radiopharmaceuticals located at http://www.cms.hhs.gov/providers/hopps/2006p/1501p.asp
†Table 1: Purchase Prices for Radiopharmaceuticals Accounting for 9% of Medicare Spending on SCODs Unit Dose http://www.gao.gov/new.items/d05733r.pdf

- The SNM supports the use of the hospital general CCR for 2006 for the determination of most radiopharmaceuticals. However, we ask that CMS recognize the general reasonable concern using the general CCR methodology for highly expensive radiopharmaceuticals due to cost compression for those radiopharmaceuticals greater than $500 in acquisition costs per patient study. For these identified radiopharmaceuticals we recommend CMS use external data to verify and pay based on invoice acquisition costs plus handling fees, and/or freeze the CY 2005 payment rates for these radiopharmaceuticals listed in Table 2 that we have identified through our members to be greater than $500 in hospital acquisition costs.

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Table 2 SNM Member Identified Radiopharmaceuticals greater than $500 per dose

HCPCS	Description	HOPPS 2005 CY Rates
A4642	Satumomab pendetide per dose	$1,390.25
A9507	Indium In 111 Capromab Pendetide, per dose	$1,915.23
A9508	Iobenguane Sulfate I-131, per 0.5 mCi	$996.00
A9517	Th I131 so iodide cap mCi	$6.57
A9521	Technetium Tc 99m Exametazime, per dose	$778.13
A9522	Indium-111 Ibritumonomabtiuxetan per mCi	N/A
A9523	Yttrium-90 Ibritumonomabtiuxetan per mCi	N/A
A9530	Th I-131 so iodide sol mCi	$9.73
A9533	I-131 tositumomab diagnostic per mCi	N/A
A9534	I-131 tositumomab therapeut per mCi	N/A
A9600	Strontium-89 chloride, per mCi	$406.16
A9605	Samarium Sm153 Lexidronamm, per 50 mCi	$907.33
C1080	I-131 tositumomab, dx, per dose	$2,241.00
C1081	I-131 tositumomab, tx, per dose	$19,422.00
C1082	In-111 ibritumomab tiuxetan, per dose	$2,419.78
C1083	Yttrium 90 Ibritumomab Tiuxetan, per dose	$20,948.20
C1093	TC99m fanolesomab per dose	$1,045.80
C1122	Tc99m Arcitumomab, per vial	$1,079.00
Q3008	Indium 111 Pentetreotide per 3 mCi	$1,079.00

Proposed Changes to Radiopharmaceutical (RP) Payment Policy in 2007

For 2007, clearly CMS is trying to come forth with an equitable solution for all radiopharmaceuticals based on cost of acquisition. We recognize that there are many factors that complicate an easy solution. We were impressed that the GAO survey acquisition cost data seemed to reflect the general experience of our members. Therefore, we believe that the GAO survey model could, in fact, be one basis for acquiring information on which a national rate setting could be established. Alternatively, recognizing the problems that manufactures may have providing certified ASP data, we ask that CMS consider and evaluate using ASP data directly from central radiopharmacies (distributors of radiopharmaceuticals.

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Radiopharmaceutical Handling Costs

CMS states in this proposed rule, "We expect that hospitals' different purchasing and preparation and handling practices for radiopharmaceuticals would be reflected in their charges, which would be converted to costs using hospital specific cost-to-charge ratios". CMS should not assume that the hospitals have incorporated handling costs in their hospital charges for radiopharmaceuticals. Please refer to Table 1. For all but one radiopharmaceutical, CMS median costs are less than the GAO data for hospital purchase prices that specifically excluded handling fees.

There has been some ambiguity about what costs should be included for radiopharmaceutical charges as opposed to procedure charges. This is complicated by the difference in policy for physician offices as compared to the hospital outpatient. Differing payment policies and lack of clear instructions in the different settings contribute to the uncertainty of where, if anywhere, radiopharmaceutical handling costs are reported by hospitals. We ask that CMS specifically declare where the costs for handling should reside for all settings and give clear direction to providers. We believe due to the variety of radiopharmaceuticals that can be used with the same procedure such as CPT 78802 *Radiopharmaceutical localization of tumor or distribution of radiopharmaceutical agent(s); whole body, single day imaging,* it is best to incorporate radiopharmaceutical handling costs in the charge for the radiopharmaceutical rather than in the nuclear medicine procedure.

CMS takes a very nice first step to giving hospitals some clarification in this proposed rule on page 42731, CMS states some of the elements to consider including in the hospital radiopharmaceutical charges, "handling cost categories should include all aspects of radiopharmaceuticals handling and preparation, including transportation, storage, compounding, required shielding, inventory management, revision of dosages based on patient conditions, documentation, disposal, and regulatory compliance." We would add that missing from this list would be time and cost for specially trained personal handling and compounding radiopharmaceuticals, as well as waste and spoilage.

Additionally, CMS should make clear where the radiopharmaceutical "*transportation*" costs should reside; that is i.e with acquisition costs or with the handling costs. For CMS information, at present, many radiopharmaceutical invoice acquisition costs could include the "transportation" costs, so we caution CMS regarding the potential for double counting. CMS should be very specific in future communications to providers regarding the components and to which portion CMS believes those cost should be attributed and specifically the *transportation* costs.

Some additional comments and concerns are also attached in addendum B in a letter addressed to Dr. Miller at MedPAC refuting their statement that handling costs are included in charges for radiopharmaceuticals .

CMS states, "we are not proposing to create separate handling categories for radiopharmaceuticals for CY 2006." The SNM is pleased that CMS does not intend to create codes for CY 2006 as we are concerned about creation of additional C or Q codes for hospitals to report their radiopharmaceutical

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handling costs in 2006 for use in 2007 at no reimbursement to the hospital for this additional work. We believe this process will place an undue administrative burden on hospitals. CMS should consider working with medical specialty societies and industry to collect this data and incorporate these added handling costs directly into the final payment rates for radiopharmaceuticals by individual HCPCS code.

To assist CMS, as requested, "we are seeking specific categories for potentially capturing radiopharmaceutical handling costs," below are some potential radiopharmaceutical handling categories;

IA	Single Photon Emitting Diagnostic Radiopharmaceutical for a nuclear medicine procedure, supplied as a unit dose
IB	Single Photon Emitting Diagnostic Radiopharmaceutical for a nuclear medicine procedure, compounded on-site
IIA	Radiopharmaceutical for a Therapeutic nuclear medicine procedure, supplied as a unit dose
IIB	Radiopharmaceutical for a Therapeutic nuclear medicine procedure, compounded on-site
IIIA	Positron Emitting Diagnostic Radiopharmaceutical for a nuclear medicine procedure, supplied as a unit dose
IIIB	Positron Emitting Diagnostic Radiopharmaceutical for a nuclear medicine procedure, compounded on-site
IV	Add-on Handling Costs associated with a Radiopharmaceutical compounded off-site, not included in acquisition costs or handling costs in categories I-III. (Use in addition to I-III above.)

New Technology

Assignment of Concurrent PET/CT for anatomic Localization

We appreciate CMS responsiveness in correcting payment rates for 78814, 78815, 78816 to restore APC placement and payments to 2005 rates in this proposed 2006 rule. As we have stated in the past, the differential in reimbursement for PET/CT and PET does not reflect the resources required to perform PET/CT. We are aware that the Academy of Molecular Imaging AMI is submitting external data in support of higher payment and reclassification for PET/CT. We support this proposal because of the higher capital and personnel costs in performing PET/CT. We ask that the data submitted be used to adjust PET/CT payment rates accordingly.

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CMS Commitment to New Technologies

CMS is proposing to change the application and review process for assignment of new services to New Technology APCs. CMS proposes to require that an application for a code for new technology service be submitted to the American Medical Association (AMA) CPT Editorial Panel before CMS will accept a New Technology APC application for review. The SNM is somewhat concerned with the proposed requirement for submission of a CPT application for a Category I or III code, prior to accepting an application for a new technology APC for review.

We appreciate the reasons for this proposal. We ask that this new criteria remain as stated, that is, that an application has been submitted to CPT but not necessarily yet reviewed and processed by the AMA CPT Panel.

Relative Weights

Packaging Issues – Dipyridamole J1245

There are currently three major pharmacological stress agents used with cardiovascular nuclear medicine procedures, Adenosine (J0152 & C9223), Dipyridamole (J1245) and Dobutamine (J1250). Dobutamine is a low cost stress agent, which is used under very specific clinical indications in nuclear medicine. Adenosine and Dipyridamole are currently commonly used stress agents in nuclear medicine currently with a K status indicator, paid for separately.

We are concerned with the CMS proposal to bundle dipyridamole into the procedure in 2006, when the reported median cost is just under $50. (The median data file on the CMS web site cost per procedure for dipyridamole is $48.85.) There are clinical situations where the physician would prefer to utilize a particular pharmaceutical stress agent. We would not want payment rules to affect a patient access to a stress agent which may be clinically most effective for him/her.

- The SNM recommends CMS maintain a status indicator of K for J1245 Dipyridamole.

Packaging Issues – CMS Clarification to Hospitals

The SNM commends CMS for the clarification and education to hospitals regarding the importance of coding and reporting charges for radiopharmaceuticals. We have seen several statements in transmittals and in federal register publications over the past year and we believe this persistent education has resulted in better data to CMS from hospitals. We believe that the CMS clarifications plus some stabilized HCPCS appropriate description codes, coupled with professional society intense education programs has lead to more accurately identified and separately paid radiopharmaceuticals as shown in the Table 3 below (Radiopharmaceutical changes in status indicator from N to K in this proposed rule).

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We support these changes and encourage CMS to continue to remind hospitals to report charges regardless of N, K or H status indicators, as these charges plays a key role in setting future APC rates and assignment of appropriate status indicators.

Table 3 Radiopharmaceutical changes in status indicators "N" to "H"

HCPCS	Description	Payment Status 2005	Payment Status 2006
A9516	Supply of Radiopharmaceutical Diagnostic Imaging Agent, I-123 Sodium Iodide Capsule, per 100 uCi	N	H
A9524	Supply of Radiopharmaceutical Diagnostic Imaging Agent, Iodinated I-131 Albumin, per 5 uCi	N	H
A9531	Supply of Radiopharmaceutical Diagnostic Agent, I-131 sodium iodide, per uCi (up to 100 microcuries)	N	H
A9532	Supply of Radiopharmaceutical Therapeutic Agent, iodinated I-125, serum albumin, 5 microcuries	N	H
C9000	Injection, Sodium Chromate Cr51, per 0.25 mCi	N	H
C9102	Supply of Radiopharmaceutical Diagnostic Imaging Agent, 51 Sodium Chromate, per 50 mCi	N	H
C9103	Supply of Radiopharmaceutical Diagnostic Imaging Agent, Sodium Iothalmate I-125 Injection, per 10 uCi	N	H
Q3006	Supply of Radiopharmaceutical Diagnostic Imaging Agent, Technetium Tc99m Glucepatate, per 5 mCi	N	H
Q3010	Supply of Radiopharmaceutical Diagnostic Imaging Agent, Technetium Tc99m Labeled Red Blood Cells, per mCi	N	H

Packaging Issues – CPT 38792

We recognize CMS and the APC Panel are not concerned with cost allocations within hospitals. If nuclear medicine costs are inappropriately bundled into surgical procedures, CMS and others believe these costs are accounted for and paid to the hospitals. CMS believes the hospital is responsible for cost accounting to get the dollars back to the appropriate department.

However, we would like to call your attention that hospitals are performing *injection- only* procedures for external sites such as surgical centers. Many surgical centers do not have the proper licenses or personnel to purchase, handle and administer radiopharmaceuticals. In these cases both the Sentinel Node injection procedure CPT 38792, and any one of the three radiopharmaceuticals listed in Table 4 are currently bundled with status indicator N. Hospitals currently have no mechanism to code and bill for this as they are not allowed to bill two bundled codes on a claim alone.

We note CMS recognized and corrected similar situations for the bladder catheterization codes CPT 51701, 51702, 51703 as well as the injection codes CPT 90783, 90784, 90788 and 90799. We agree that

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this was appropriate to change status indicators from N to X for these codes. The SNM believes this is a similar situation for CPT 38792. We believe the resources and clinical similarities warrant placement for 38792 in this APC 0359 with a status indicator of X.

Table 4 Radiopharmaceuticals Used for Sentinel Node Procedures

HCPCS Code	Status Indicator	Description
A9520	*N*	*Supply of radiopharmaceutical diagnostic imaging agent, technetium 99mTc sulfur colloid, per millicurie*
A4641	*N*	*Supply of radiopharmaceutical diagnostic imaging agent, not otherwise classified*
A9512	*N*	*Supply of radiopharmaceutical diagnostic imaging agent, technetium 99mTcpertechnetate, per millicurie*

- The SNM recommends CMS change the status indictor for CPT 38792 from N to X and place in APC 0359 in 2006.

APC Assignments

Relocation Issues – CPT 78730

Last year we brought to the attention of CMS that CPT 78730 is a nuclear medicine *imaging procedure*. We also brought to your attention that the high volume and low median cost data was due to inappropriate use by other specialties. Since that time, the SNM has notified AdminaStar Federal of the need for CCI edits.

At the February 2005 APC panel meeting the, *The Panel recommends* that CMS move CPT code 78730, urinary bladder residual study, to APC 404, assuming that new data confirmed that previous data were derived from incorrectly coded hospital claims.

However, CMS has failed to restore CPT 78730 to APC 404 as requested in our October 2004 and the January 2005 comments. CMS further suggested that a nuclear medicine technologist is not needed to perform this procedure; we continue to disagree with this CMS statement. This procedure is a nuclear medicine imaging procedure, which we believe has been historically miscoded in combination with non-imaging urological procedures. Placement of CPT 78730 Urinary bladder last year resulted in a 30.58% reduction in payment. While we recognize CMS made these decisions based on miscoded claims, this issue of miscoded claims should be resolved for 2006 and therefore CMS should restore CPT 78730 to its correct APC grouping 0404.

- The SNM recommends CMS restore 78730 to APC 0404.

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Relocation Issues – CPT 78700

The SNM has identified another procedure, CPT 78700 (Kidney imaging, static) which the CMS proposes to move from APC 0404 to 0267 *Level III Diagnostic ultrasound.* This change represents a 30.58% reduction in payment from 2005. The SNM is concerned with the CMS process and rational for moving APCs from clinically similar APCs to an unrelated non-clinically homogenous APC. CMS appears to make these decisions strictly on hospital costs reduced to charges and not aligning the procedures in APCs that are clinically similar.

At this time, we are unsure why CMS data has shown a shift in the costs of CPT 78700 Kidney imaging; static only. This procedure has NOT clinically or economically changed. We suggest that when CMS moves a CPT from one APC to another and the payment is increased or decreased by more than 10%, CMS should provide rational for why the move was necessary and why they choose the particular placement. This would allow the community opportunity to comment on the CMS rational as well as the placement.

- The SNM recommends CMS restore 78700 to APC 0404.

We thank you for your attention and consideration of these recommendations and comments. We look forward to continue working with CMS as we refine the Nuclear Medicine Procedure and Radiopharmaceutical APCs. If you need additional information, please contact the SNM staff, Denise Merlino at 781-435-1124 or dmerlino@snm.org.

Respectfully Submitted,

Gary Dillehay, M.D., FACR, FACNP
Chairman, Coding & Reimbursement Committee

Kenneth McKusick, M.D., FACR, FACNP
SNM Coding Advisor

cc: Herb Kuhn, CMS
Kenneth Simon, MD, CMS
Edith Hambrick, MD, CMS
James Hart, CMS
Joan Sanow, CMS
SNM Coding & Reimbursement Committee
Nuclear Medicine APC Task Force

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Addendum A

July 11, 2005

To: Kenneth Simon M.D.
Re: Coding for PET/CT plus Diagnostic CT

CPT codes 78814-16 were first published in CPT 2005 to report tumor PET functional imaging in CT anatomical space. Over two years ago, when the Society of Nuclear Medicine Inc and American College of Radiology applied for those new codes, *Tumor PET combined with concurrent CT for both attenuation correction and anatomical localization: limited, torso,* or *whole body*, it was not thought that diagnostic quality CT data could or would be acquired during the CT phase of the study. Now, however, state of the art PET/CT integrated systems can acquire CT data for attenuation correction, anatomical localization and CT diagnosis simultaneously.

This was not anticipated. Although CPT does instruct users to add modifier 59 to a CT study done in addition to a PET/CT study, it was our general understanding at the time, that this would be for those uncommon occurrences that a separate CT study might be indicated on the same day as the PET/CT study (e.g. a chest CT for possible pulmonary embolism on the same say as a PT/CT done for neoplasm restaging).

Diagnostic CT studies are being requested by referring physicians and done not uncommonly with PET/CT studies on the same day. There are several possible acquisition scenarios:

1. Separate diagnostic CT(s) done on a CT device separate from the PET/CT.
2. Separate diagnostic CT(s) acquisition done after the PET/CT study (where the first CT data acquisition, done without contrast and as part of the PET/CT study, may be done at less than state of the art diagnostic quality using low maS for attenuation correction and anatomic localization, on the same device.
3. Diagnostic CT(s) done as part of the attenuation correction and anatomical phase of the PET/CT study.

The technical resources required to obtain the imaging data would not be the same for all three, even though the final product would be the same: a PET/CT study with anatomical localization and one or more diagnostic CTs, (e.g. chest, abdomen and/or pelvis.
#1 requires a minimum three imaging acquisitions (one PET and two CT) on two devices, #2 requires these three imaging acquisition on one device, and #3 requires a minimum of two imaging acquisitions (one PET and one CT) on one device.

As discussed with you, we would like to meet with CMS to discuss the current state of PET/CT imaging in oncology, and to develop a common understanding of the possible resource costs associated with the various imaging algorithms. The American College of Radiology, the Academy of Molecular Imaging and the Society of Nuclear Medicine, Inc would attend.

Ken McKusick M.D
Society of Nuclear Medicine

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Addendum B

Aug 2, 2005

Via email

Mark Miller, Ph.D.
Executive Director, MedPAC
601 New Jersey Ave. N.W.
Suite 9000
Washington, DC 20001

RE: Request for Clarification: June 2005 MedPAC Report – Pharmacy Handling Costs in Hospital Outpatient Departments for Radiopharmaceuticals

Dear Dr. Miller:

On behalf of the Nuclear Medicine APC Task Force (NM APC TF), I thank you and your staff for taking the time on the conference call last May 25th, as well as the in person meeting on November 3, 2004 to discuss your report to Congress on the handling costs for radiopharmaceuticals and other products in the hospital outpatient department. Since then, your June 2005 Report to Congress was released which captured many of the unique overhead and handling costs related to radionuclides and radiopharmaceuticals ("RPs"). This letter provides additional clarification and follow-up on an issue important to any policy making on Medicare payment for radiopharmaceuticals.

The NM APC TF agrees with your primary finding that among the categories of products, RPs require unique resources including special equipment and protection for patients and staff during storage, preparation, and disposal, which, in turn, lead to higher costs. Further, hospitals must ensure and document compliance with federal and state requirements.

The NM APC TF is troubled by the MedPAC statement referring to commercially prepared patient unit doses that "the invoices for the product combines handling costs with acquisition costs and delivery fees" (June 2005 Report, Ch. 6, page 147). Although this statement is true regarding some handling costs in preparation that would otherwise be done "in-house", we believe this is misleading to CMS and others should MedPAC's choice of words be taken literally. Simply stated, a minor part of the routine handling costs are covered by invoices for commercially prepared unit doses. A more accurate statement might be that "invoices for the product *may* combine some of the handling costs etc. We support CORAR's comment in their recent letter to you, that "all hospital outpatient departments (both "make" and "buy" models) that furnish radiopharmaceuticals (unit dose or components) must purchase special shielding equipment and dose calibrators, monitor employee exposure to radiation, employ radiation safety officers, and comply with specific regulations regarding radioactive material, waste, storage, and disposal, licensure, quality assurance and safety. Freestanding independent radiopharmacies that distribute and sell unit-dose radiopharmaceuticals do not factor in on an invoice the unique hospital handling costs related to, among other things, licensure, safety, employee monitoring, and quality

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assurance. Therefore, it would be incorrect to imply **all** pharmacy handling costs for unit-dose radiopharmaceuticals are included on an invoice from an outside vendor."

The MedPAC study on pharmacy costs associated with RPs may be the first to specifically analyze the handling and overhead costs and resources associated with RPs. Thus, your report may be accorded great weight in decisions regarding payment for RPs. The NM APC TF would appreciate a statement from MedPAC that qualifies the original statement. Specifically, we ask that MedPAC write to CMS and clarify that invoices for unit dose preparations do **not** include **ALL** the hospitals' handling costs such as those associated with receiving the RP, dose measurements and quality assurance tests prior to administration, storage, disposal, regulatory compliance, and safety

The NM APC TF would be pleased to discuss this further with MedPAC. In light of the published proposed HOPPS rule, the NM APC TF also intends to meet with CMS to help clarify and assist in the development of HOPPS payment policy that accurately reflects overhead costs for radiopharmaceuticals.

We thank you for your attention and consideration of these recommendations and comments. If you need additional information, please contact the NM APC TF staff, Denise Merlino at 781-435-1124 or dmerlino@snm.org.

Sincerely,

Kenneth A. McKusick, MD FACR FACNP
Chair, Nuclear Medicine APC Task Force

cc: Rachel Schmidt, Ph.D., MedPAC (via email)
Sarah Thomas, M.S.; MedPAC (via email)
Don Thompson, Director, Hospital and Ambulatory Policy Group, CMS (via email)
Edith Hambrick, M.D., J.D., Chair, APC Panel (via email)
NM APC TF members (via email)

Submitter : **Ms. Denise Merlino** **Date: 09/15/2005**

Organization : **Nuclear Medicine APC Task Force**

Category : **Other Association**

Issue Areas/Comments

GENERAL

GENERAL

Comments are in attached PDF File

CMS-1501-P-449-Attach-1.PDF

NUCLEAR MEDICINE APC TASK FORCE

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American College of Nuclear Physicians
American College of Radiology
American Society of Nuclear Cardiology
Council on Radionuclides and Radiopharmaceuticals, Inc.
National Electrical Manufacturers Association
Society of Nuclear Medicine
Society of Nuclear Medicine - Technologist Section

September 15, 2005

Submitted Electronically: http://www.cms.hhs.gov/regulations/ecomments

Administrator Mark McClellan M.D. PhD
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
ROOM 445-G
200 Independence Avenue, S.W.
Washington, DC 20201

ATTN: FILE CODE CMS-1501-P

Re: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; Proposed Rule

Dear Administrator McClellan:

We are writing in response to the proposed 2006 Hospital Outpatient Prospective Payment System (HOPPS) Rule, 70 Fed. Reg. 42673, July 25, 2005. The Nuclear Medicine APC Task Force (TF) is pleased to submit these comments to assist the Centers for Medicare and Medicaid Services (CMS) in further refining the proposed HOPPS payment rules for 2006. CMS proposes substantive changes in payment methodologies for radiopharmaceuticals both for 2006 and 2007; we recognize and appreciate the complexity of the HOPPS program. Therefore, we appreciate CMS willingness to understand and account for the unique and varying attributes of radiopharmaceuticals used with Nuclear Medicine procedures provided to Medicare beneficiaries. We look forward to working with CMS collaboratively as you respond to our concerns and recommendations.

"Non-Pass-Throughs"
Radiopharmaceutical (RP) Payment Policy Changes 2006 & 2007

CMS proposes to implement, "a temporary 1-year policy for CY2006 to pay for radiopharmaceutical agents that are separately payable in CY 2006 based on the hospital's charge for each radiopharmaceutical agent adjusted to cost." ***The TF agrees with the implementation in CY2006 of this policy, with the essential clarification that CMS should use the hospital general cost to charge ratio (CCR) and not a department specific CCR*** to make

this adjustment. Several of our member organizations have submitted detailed comments, and we will not repeat those details in these comments.

In addition, we do **not** believe that a CCR method to determine the cost of supplying radiopharmaceuticals is without problems. We are **especially concerned about the effect of cost compression using a CCR.** Hospitals do not tend to maintain a constant CCR as radiopharmaceutical costs increase. As radiopharmaceutical costs increase, the documented differences between actual cost data and CMS derived cost data increase exponentially. We ask that CMS recognize this and consider measures to address this phenomenon. CMS may want to consider a national and unique cost to charge ratio for radiopharmaceuticals. Our member organizations have submitted detailed comments regarding cost compression.

For Y2007 and forward, we ask that the CMS carefully review and analyze radiopharmaceutical costs acquired in Y2006 using CCR, and consider to continue using CCR along with other options supplied by our member organizations. ***We ask CMS to consider the impact to the payment system and the burden to hospital regarding significantly changing payment methods for radiopharmaceuticals from year to year, and ask that the CMS consider using a refined CCR method for a period of time beyond just the Y2006.***

Radiopharmaceutical Handling Costs

The TF **strongly disagrees** with the CMS and MedPAC conclusion that hospitals have accounted for ALL their costs directly or indirectly related to both the acquisition cost and handling fees for radiopharmaceuticals. We reference our letter sent to MedPAC as follows: "The NM APC TF is troubled by the MedPAC statement referring to commercially prepared patient unit doses that "the invoices for the product combines handling costs with acquisition costs and delivery fees" (June 2005 Report, Ch. 6, page 147). Although this statement is true regarding some handling costs in preparation that would otherwise be done "in-house", we believe this is misleading to CMS and others should MedPAC's choice of words be taken literally. Simply stated, a minor part of the routine handling costs are covered by invoices for commercially prepared unit doses. We support CORAR's comment in their recent letter to you, that "all hospital outpatient departments (both "make" and "buy" models) that furnish radiopharmaceuticals (unit dose or components) must purchase special shielding equipment and dose calibrators, monitor employee exposure to radiation, employ radiation safety officers, and comply with specific regulations regarding radioactive material, waste, storage, and disposal, licensure, quality assurance and safety. Freestanding independent radiopharmacies that distribute and sell unit-dose radiopharmaceuticals do not factor in on an invoice the unique hospital handling costs related to, among other things, licensure, safety, employee monitoring, and quality assurance. Therefore, it would be incorrect to imply **all** pharmacy handling costs for unit-dose radiopharmaceuticals are included on an invoice from an outside vendor."

Over the years, we have seen little direction or clarification to hospitals from CMS regarding what is considered appropriate to include in setting charges for radiopharmaceuticals in addition to the acquisition cost. ***The TF believes that CMS must release an official, detailed definition of what providers should include in radiopharmaceutical charges to cover the recognized (MedPAC) high handling costs inherent to the use of radiopharmaceuticals.*** If CMS does not make clear what it approves to be included for radiopharmaceutical handling, then the reported charges will vary considerably across hospitals, compromising the CMS' future ability to create accurate radiopharmaceutical handling payment rates.

CMS states, "we are not proposing to create separate handling categories for radiopharmaceuticals for CY 2006." However, the CMS is proposing to request handling cost data from the hospitals and requested advice about defining categories to acquire this data. We are concerned about the usefulness of creation of additional C or Q codes for hospitals to report radiopharmaceutical handling costs in 2006 for use in 2007 at no reimbursement to the hospital for this additional work. We believe this process will place an undue administrative burden on hospitals. Our member organizations have drafted detailed comments on categories that would reflect the specific handling costs of radiopharmaceuticals for CMS to consider. ***We strongly recommend CMS work with medical specialty societies and industry to develop these categories. If the CMS wishes to use them to collect more data about handling costs, then we request that the CMS set payment for each category to help deflect the additional cost to hospitals for this added burden and to ensure adequate data collection. In addition, we ask for concurrent direction to the hospitals about including the cost of handling into their charges for radiopharmaceuticals.***

"New Technology"
Assignment of Concurrent PET/CT for anatomic localization

We appreciate CMS responsiveness in correcting payment rates for 78814, 78815, 78816 to restore APC placement and payments to 2005 rates in this proposed 2006 rule. However, we support our member organization the Academy of Molecular Imaging request for adjusted rates based on external data. The TF is concerned that the CMS is not aware of the major clinical usefulness of the appropriate application or additional expenses associated with concurrent PET imaging with CT for anatomical localization. We are concerned that the corrected proposed payment rates do not adequately cover hospitals costs for providing PET/CT services. **We strongly support their recommendation for CMS to use external data and adjust PET/CT payment rates accordingly.**

Reporting a Diagnostic CT on Same DOS as PET/CT

Several TF members recently met with CMS, regarding appropriate reimbursement for diagnostic CT when performed in conjunction with PET/CT (CPT 78814-16). The specific concern was appropriate reimbursement for a diagnostic CT study when acquired as part of the same data set as for the PET/CT study itself (what is referred to as a "*single CT acquisition*"). Oncology practice is changing as the clinical usefulness of PET/CT technology is learned and applied. Although not yet widely adopted, increasing numbers of facilities are capable and currently performing *single CT acquisition* when their referring physicians order diagnostic CT and PET/CT. Many of the technical resources for acquiring diagnostic CT data are the same as for the CT for attenuation correction and anatomical localization of the PET/CT, when only *a single CT acquisition* is performed. However, the initial capitol costs are greater for a PET/CT capable of performing diagnostic CT, and there are added costs for acquiring the diagnostic CT data such as for the contrast agent and for appropriate nursing and technical personnel. These were not assumed for any previous cost determination, such as for the PEAC, for doing a PET/CT. ***The TF is supportive of continued discussion with the CMS on this issue of***

appropriate payment for the technical costs of performing a diagnostic CT acquired simultaneously with a PET/CT.

"Multiple Diagnostic Imaging Procedures"

CMS proposes to implement the MedPAC recommendation to "reduce the technical component payment for multiple imaging services performed on contiguous body parts." Specifically, CMS proposes to make full payment for the procedure with the highest APC payment rate and to make a 50% reduction in the OPPS payments for some second and subsequent imaging procedures performed in the same session. The TF agrees with the CMS position that, when some of the procedures identified by CMS are performed in the same session, some of the resource costs are not incurred twice. However, the TF has serious concerns about the CMS methodology to analyze this position.

We support the ACR and NEMA regarding their request for at least a one-year delay regarding the adoption of the proposed payment reductions for multiple diagnostic imaging procedures and with medical specialty and industry undertake a complete study of clinical practice patterns prior to implementing.

We thank you for your consideration of these comments. The proposed policy changes for PET/CT and for radiopharmaceuticals will have a significant impact on the nuclear medicine community. ***The NM APC TF will request a meeting with CMS to discuss payments for radiopharmaceuticals and handling fees in 2006.*** We look forward to working with the CMS to develop a workable solution for all stakeholders. If you need additional information, please contact the NM APC TF staff, Denise Merlino at 781-435-1124 or dmerlino@snm.org.

Sincerely,

Kenneth A. McKusick, MD FACR FACNP
Chair, Nuclear Medicine APC Task Force

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